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RESULTS OF THE PILOT TESTING OF HACCP SYSTEMS IN NINE VOLUNTEER MEAT AND POULTRY PLANTS

(U.S.) FOOD SAFETY AND INSPECTION SERVICE, WASHINGTON, DC. SCIENCE AND TECHNOLOGY

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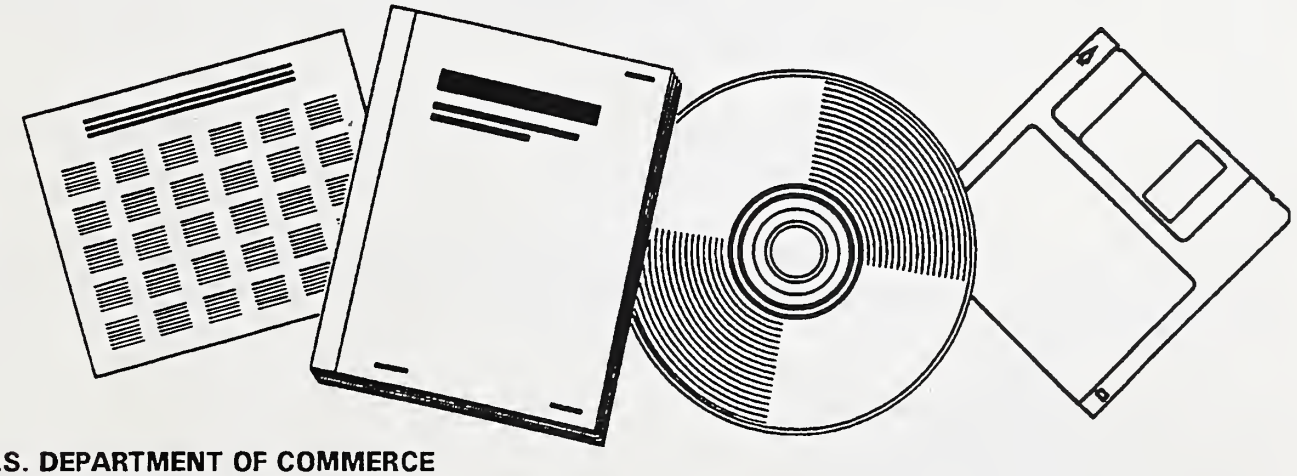

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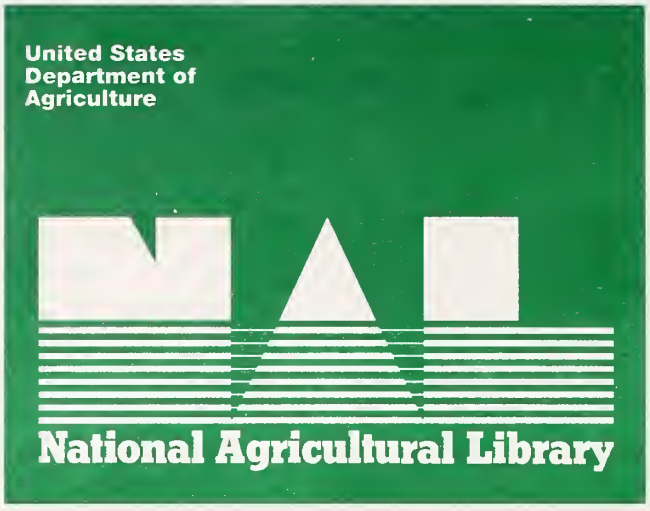

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Science and
Technology

HACCP 11

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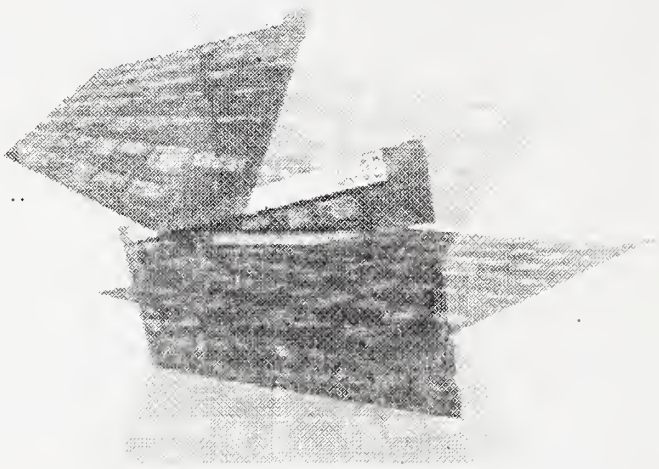

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U.S. Department of Agriculture
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April 1995

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In January 1990, the Food Safety and Inspection Service of the U.S. Department of Agriculture initiated efforts to determine how to implement the Hazard Analysis and Critical Control Point (HACCP) system in regulated meat and poultry plants. HACCP is a process control system that identifies "critical" points in the food production process that should be controlled to prevent food safety hazards from occurring.

Agency activities included consultations and public hearings to explain HACCP and the Agency's efforts, workshops to develop model HACCP plans, inplant testing to trial the specific plant HACCP plans at nine volunteer plants, and an assessment of the overall experience of the Agency.

A series of reports have been written on the various phases and activities undertaken by the Agency and participants during the study. This report is one of the reports.

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In January 1990, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture initiated efforts to determine how to implement the Hazard Analysis and Critical Control Point (HACCP) system in regulated meat and poultry plants. HACCP is a process control system that identifies "critical" points in the food production process that should be controlled to prevent food safety hazards (i.e., microbiological, chemical, and physical hazards) from occurring.

Agency activities included consultations and public hearings to explain HACCP and the Agency's efforts, workshops to develop model HACCP plans, in-plant testing to trial the specific plant HACCP plans at nine volunteer plants, and an assessment of the overall experience of the Agency.

A series of reports have been written on the various phases and activities undertaken by the Agency and participants during the study. This is one of the reports. For further information concerning FSIS HACCP activities contact:

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EXECUTIVE SUMMARY

Background

In the late 1980's the Food Safety and Inspection Service (FSIS) began encouraging the meat and poultry industry to implement the Hazard Analysis and Critical Control Points system (HACCP). FSIS began focusing on HACCP in 1989. At that time, Agency planners envisioned HACCP as a voluntary program.

The Agency set forth four major initiatives: (1) **consultations and public hearings**; (2) **three-day workshops** to develop generic HACCP models; (3) **development of plant-specific HACCP plans** for selected product classes that would be used for in-plant pilot testing; and **assessment of plant-specific HACCP plans** in a case study.

The Agency's primary concerns involved: pre-implementation stages for HACCP models in volunteer plants; conformance of generic models and plant-specific plans with HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF); functioning of plant-specific HACCP models in volunteer plants; and functioning of a HACCP-based inspection system in volunteer plants.

FSIS conducted workshops during 1991 and early 1992 to develop generic HACCP models for pilot testing in five process areas: refrigerated foods, cooked sausages, poultry slaughter (young chickens), ground beef, and swine slaughter. The model plans identified Critical Control Points (CCP's) and methods for controlling, monitoring, and verifying control at CCP's. The model plans for refrigerated foods (RF), cooked sausages (CS), and poultry slaughter (PS) were pilot tested. Concurrent with the workshops, FSIS published a *Federal Register* notice to solicit volunteers to pilot test the generic HACCP models developed at the workshops. Nine establishments volunteered for pilot testing - three for each of the three process areas. These establishments were to develop and implement their own plant and process-specific HACCP plans based on the generic HACCP models.

Scope

The HACCP case study was designed to provide the Agency with tangible experience with voluntary HACCP in meat and poultry establishments. The evaluation of plant-specific HACCP plans involved three phases of data collection: **Baseline** (Phase I), **Implementation** (Phase II), and **Operational** (Phase III). In Phase I, FSIS collected baseline data for at least three months. Each plant continued to operate as it had in the past, while developing its own specific HACCP plan based on the workshop generic models. In Phase II, Agency inspectors and plant personnel were trained in HACCP. Plant personnel adjusted to the new pattern of HACCP-controlled operations, found and corrected process control discrepancies, and adjusted the plan where necessary. Phase III began when the Agency and plant management agreed that the plant-specific HACCP plan was ready to be operational.

In the initial stages, each generic model and each plant's specific HACCP plan was assessed using checklists based on the HACCP principles of the NACMCF.

Quantitative analyses were performed for microbiological organisms and indicators, and for chemical and physical factors relevant to microbiological status. FSIS developed sampling plans, selected analytical test procedures, and designed survey instruments.

> Microbiological sampling and testing provide information about a food manufacturer's process. Tests were selected to recover a wide range of pathogenic and non-pathogenic microorganisms capable of growing in product and plant environments under varying conditions and at different points in the process.
>
> Chemical factors were used to supplement the microbial testing and to aid in evaluating any observed microbial changes. In CS plants, samples were collected for determination of nitrites and brine. In addition, samples of curing mixtures were collected for nitrite testing. For poultry slaughter, sampling of total chlorine in water was done daily with the water being sampled as it entered the chiller.
>
> "Physical factors" refers to product attributes or processing characteristics that have an effect on the final product's wholesomeness or safety. FSIS constructed a series of data collection tasks for each product type to assess plant control of the physical factors.

Qualitative data were gathered from plant records, plant personnel, and inspection personnel using various surveys, questionnaires, and data collection instruments. The general concern was management commitment to process controls, quality, regulatory compliance, and HACCP training. Qualitative factors specifically related to sanitation, hygiene, plant personnel attitudes, and commitment to producing a wholesome and safe product.

Industry and Agency training for HACCP was conducted at the pilot plants just before Phase II to familiarize both plant and inspection personnel with HACCP principles. The training was assessed to determine how well it functioned; to gain insight into the training needs of inspectors working in a HACCP-based inspection system and the content needed in HACCP training; to begin consideration of the target population for HACCP training; and to learn about the best formats for delivering such training.

Accomplishments

The **HACCP model checklist** was used to compare each plant's specific plan against the 1989 NACMCF principles.

All plans conformed highly to the 1989 recommendations of the NACMCF, with the lowest score being 97 percent in conformance. In general, the plans presented adequate information and detail to provide the basis for a HACCP plan.

Significant **quantitative data** were collected on the microbiological status of the product and plant environment, including supplementary chemical and physical factors.

Qualitative data provided an overview of the plant's processing or slaughter environment with respect to the management's commitment to controlling the manufacturing process and to quality and regulatory compliance.

The **HACCP literature review**, published in April 1994, surveyed the origins of HACCP and its evolution and the application of HACCP in various segments of the food industry.

HACCP Workshops were conducted and generic models were published in reports, also in April 1994.

Training surveys provided feedback to the Agency for use in developing long-range plans for HACCP training.

The plant results gave valuable insights and lessons that have and will continue to help FSIS implement HACCP over the next several years. The information and data collected from the voluntary HACCP pilot study were used in the development of the Agency's Pathogen Reduction/Hazard Analysis and Critical Control Point systems proposed regulation, which was published in the *Federal Register* of February 3, 1995. Data on plan development and implementation were invaluable in developing and analyzing the cost impact of the proposed rule. The experience of volunteer plants in using generic models that they could adapt to meet their specific needs was reflected in the proposed rule-making. The training experiences of the pilot study have helped to shape the Agency's plans in this area.

PREFACE

The case study reported here was undertaken to provide the Agency with tangible experience with HACCP in federally-inspected meat and poultry establishments. It was *not* intended to determine HACCP's effectiveness, which has been recognized by the scientific community, industry, and government for many years.

The Agency's planning and activities for the HACCP study began in 1989 and ran into 1993. This complex project was overtaken by several events during this period:

> The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP principles set forth in 1989 were the basis for the study design; the NACMCF changed the application of the principles in 1992, late in the project's course.
>
> In 1993 the NACMCF published *The Role of Regulatory Agencies and Industry in HACCP*, again re-defining the basic context for considering HACCP.
>
> In 1993 the USDA made a significant change in policy from envisioning HACCP as a voluntary process to proposing that it become mandatory for all federally-inspected meat and poultry establishments.

The last event is particularly important. Before this study, the Agency's experience in this general area had been limited to Total Quality Control (TQC) systems, which are voluntary. The new focus on mandatory HACCP food safety systems has introduced many additional questions as to how HACCP should be implemented across the entire meat and poultry industry.

After considering how to report on a study spanning a period in which the regulatory context changed dramatically, the decision was made to issue a complete report, with all the data presented, while focusing on the elements of the study that directly influenced Agency thinking on the Pathogen Reduction/Mandatory HACCP proposed regulation published in the *Federal Register* of February 3, 1995. Data on plan development and implementation were invaluable in developing and analyzing the cost impact of the proposed rule. The experience of volunteer plants in using generic models that they could adapt to meet their specific needs was reflected in the proposed rule-making. The training experiences of the pilot study have helped to shape the Agency's plans in this area.

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CHAPTER I

HACCP ANALYTIC STUDY OF THE IMPLEMENTATION OF HACCP SYSTEMS IN NINE SELECTED MEAT AND POULTRY PLANTS

BACKGROUND:

In the late 1980s, FSIS set as a long-range goal, the implementation of HACCP in all meat and poultry inspection activities. FSIS had begun planning for HACCP in 1989. In May 1993 Secretary of Agriculture Mike Espy directed that FSIS present him with a plan for making the HACCP system of process control mandatory in the nations's federally-inspected meat and poultry plants.

During its initial planning phase, the Agency had identified the following four major initiatives:

(1) consultations and public hearings to solicit views from FSIS employees, professional organizations, consumer and other public interest groups, and industry (January through July 1990);

(2) workshops facilitated by FSIS personnel to develop model or generic HACCP plans and plant-specific HACCP plans for selected product classes (February 1991 through April 1992);

(3) development of plant - specific HACCP plans for selected product classes that would be used for in-plant pilot testing (June 1991 through August 1993); and

(4) assessments of the HACCP models and the pilot tests using a case study approach.

CONSULTATIONS:

In 1990, FSIS held consultations and public hearings to solicit views on potential elements of its HACCP study from interested parties. Eight topics emerged from the consultations:

1. Selection of specific products and processes as subjects for workshops to develop model HACCP plans;

2. Objectives and format for the workshops;

3. Role of the FSIS HACCP Special Team -- seven Agency employees with strong backgrounds in all areas of inspection who would facilitate the workshops and direct in-plant training, testing, and assessment;

4. Selection of volunteer plants to pilot test plant-specific HACCP plans developed through use of generic models;

5. Criteria for assessing HACCP plans;

6. Follow-up with interested parties during and after the pilot testing;

7. Reporting and disseminating the core study conclusions; and

8. HACCP training needs for both FSIS inspectors and industry personnel.

FSIS identified seven tasks that should be assessed during the pilot (See Table 1). Results from some of these tasks were to be reviewed by experts from outside of FSIS -- including other government agencies, industry, and academia -- while others were not.

TABLE 1: HACCP IMPLEMENTATION ASSESSMENT TASKS

External Review	Internal FSIS Review
National Profiles	Workshop Evaluation
HACCP Model Checklist	Training
Quantitative Plant Data (Microbiological, chemical, and physical)	
Qualitative Plant Data	
Literature Review	

This report will discuss the detailed findings of key areas. More specifically, the national profiles present an overview of the industry, the particular HACCP pilot program areas (Ready-to-eat Refrigerated Foods, Cooked Sausages, and Poultry Slaughter (young chickens)), and each of the nine volunteer plant participants. The HACCP Model checklist was used to compare each generic model and each pilot plant's specific plan against the 1989 National Advisory Committee on Microbiological Criteria for Foods (NACMCF) principles (Reference 1). Quantitative data on microbiological, chemical, and physical factors were collected for baseline information and comparisons made with operational data. The quantitative data were collected for safety-related areas and, where appropriate, at critical control points, control points, and finished product. Quantitative

data were collected to obtain an understanding of what might transpire during HACCP implementation and identify possible effects of the implementation on the industry. The qualitative data provided an overview of the plant's managerial environment (i.e. management's commitment and willingness to control the manufacturing process and its commitment and attitude toward quality and regulatory compliance based on product impact on consumer health and safety). The results of the Workshops were presented in four reports which were published also in April 1994. (References 2 through 5) The HACCP Literature Review was published in April 1994. (Reference 6) The training survey results provided feedback to the Agency for use in developing long-range plans for HACCP training.

WORKSHOPS FOR DEVELOPING MODEL HACCP PLANS:

FSIS conducted workshops, during 1991 and early 1992, to develop generic HACCP models for pilot testing. The workshops were held over a three-day period with approximately one-and-a-half days devoted to training in HACCP principles and one-and-a half days devoted to generic plan development. The workshops developed generic HACCP models for five product or topic areas: refrigerated foods, cooked sausages, poultry slaughter (young chickens), ground beef, and swine slaughter. Only the first three model plans were pilot tested.

The Agency facilitated the workshops, which industry technical representatives attended. The model plans identified CCP's and methods for controlling, monitoring, and verifying control at CCP's. Participants in each workshop established a Steering Committee to refine the generic HACCP plans in cooperation with FSIS. FSIS also selected "subject matter experts" (SME's), Agency in-plant inspection employees who provided technical expertise and guidance on specific products or processes to the workshops and steering committees. Table 2 lists the topic areas, locations, and dates of the five workshops, and the number of participants and observers in each workshop. Workshop participants represented industry, trade associations, and government. The workshops were open to the public for observation, on a reserved space basis. Time was allotted for observer comments, but observers were not allowed to participate in developing model plans.

TABLE 2: GENERIC HACCP MODEL PLAN DEVELOPMENT: Locations, Dates, and Number of Participants and Observers

Model/Topic Area	Location	Dates	Number of Participants*	Number of Observers**
Refrigerated Foods	Baltimore, Maryland	February 26-28, 1991	40	12
Cooked Sausages	Fort Worth, Texas	May 21-23, 1991	35	25
Poultry Slaughter	Atlanta, Georgia	August 27-29, 1991	43	54
Fresh Ground Beef	Phoenix, Arizona	December 3-5, 1991	31	12
Swine Slaughter	Minneapolis, Minnesota	March 31 - April 2, 1992	30	6
5 Topic Area Totals			179	139

* Participants - representatives from industry, trade associations, and other non-FSIS government Agencies.

** Observers - Open to general public for observation, with time allotted for comments, but observers were not allowed to participate in model development.

More detailed findings of the workshops are found in the previously referenced reports. Detailed information on the five generic models developed in the workshops appears in the following publications: 1) Generic HACCP Model for Refrigerated Foods; 2) Generic HACCP Model for Cooked Sausages; 3) Generic HACCP Model for Poultry Slaughter; 4) Generic HACCP Model for Ground Beef; and 5) Generic HACCP Model for Swine Slaughter (References 7 through 11). The Agency conducted a literature review of the origins of HACCP and its evolution. The literature review discusses the application of HACCP in various segments of the food industry (Reference 6).

DEVELOPMENT AND ASSESSMENTS OF PLANT-SPECIFIC HACCP PLANS AND PILOT TESTS

This report details the methodology utilized in conducting the nine plant-specific HACCP plans' development and the analysis of the individual plant's implementation and operation of their respective HACCP plan. Chapter II discusses the methodology while Chapter III presents the analysis and findings of the HACCP pilot program.

CHAPTER II

ANALYTIC STUDY METHODOLOGY FOR THE IMPLEMENTATION OF HACCP SYSTEMS IN NINE SELECTED MEAT AND POULTRY PLANTS

ANALYTIC STUDY METHODOLOGY:

Generally, the goal of research is to be able to extrapolate from the study results to the population that is being studied. However, many factors affect the ability to conduct true experimentally-designed research (see Campbell, D. T., and Stanley, J. C., 1963; and Kidder, L. H., and Judd, C. M., 1986 - References 12 and 13). Examples are: resource constraints in terms of dollars and personnel, participation of subjects, length of time needed to conduct the research, and length of time needed to see changes in the experimental group. Well-controlled experimental research designs are the ideal way to conduct research because they allow random assignment of subjects to the experiment, so that the researcher can control the influence of potentially compounding variables. Such designs use random selection (random sampling) of the subjects to be studied. There is a "treatment group," which is subjected to whatever is being tested, and a "control group," which is not subjected the treatment. However, this is not always possible.

For practical reasons, FSIS chose to use an analytic study design which involved a pretest-posttest case study approach. The analytic study design is defined by Dr. W. Edwards Deming as "one in which action will be taken on a cause-and-effect system to improve performance of a product or a process in the future" (Reference 14). In an analytic study, researchers aim for prediction that a particular process, product, or material is superior to others in the future. Because there is no existing universe in an analytic study, the study is conducted on judgment samples because the judgment of experts in the subject matter defines conditions to be studied and measurements to be taken for each set of conditions. Analytic studies are generally conducted on prototypes to learn how the product and/or process will function years later in the field. The analytic study's environment is usually not static, but rather it is dynamic with the primary source of uncertainty lying in identifying which variables will have the most significant impact on future outcomes of the process.

Agency resources for program testing were limited, thereby limiting the number of pilot plants that could participate in the study. The Agency felt that a multilevel, incremental HACCP pilot study would help the industry and Agency better understand the concept and better prepare the Agency for future nationwide implementation.

DATA LIMITATIONS:

The HACCP case study was not designed to provide information on the value of HACCP. The scientific community has already established HACCP's value. The case study was undertaken to provide the Agency with tangible experiences in implementing HACCP in meat and poultry establishments.

The limitations of this case study approach are partly due to the fact that HACCP plans were pilot-tested in nine plants that volunteered. Because plants vary greatly, the pilot test results cannot be extrapolated to all meat and poultry plants. Inference can only be made to the volunteer plants.

Testing was conducted on the normal production system of the plants with no introduction of anomaly batches or lots to ensure that all types of batches or lots were tested. It was assumed that many different conditions of lots or batches would be encountered. It was not possible to test for seasonal variations or other uncontrollable variables.

Because only a limited number of on-site reviews were conducted, the analysis of the qualitative data could be biased by day-to-day operational variability. It would have been preferable to review each plant more than once to collect both "pre-HACCP" and "post-HACCP" data, but resource constraints prevented this.

SOLICITATION OF PLANT PARTICIPATION:

Concurrent with the workshops, FSIS placed in the Federal Register a notice to solicit volunteers to pilot test the generic model HACCP plans developed at the workshops (Reference 15). Because of resource and time constraints, FSIS pilot tested generic HACCP model plans for only three areas -- Refrigerated Foods, Cooked Sausages, and Poultry Slaughter (young chickens). Nine meat and poultry establishments volunteered for pilot testing (three for each product process area). These establishments developed and implemented their own plant and process-specific HACCP plans based on the generic HACCP models.

Before testing the plant-specific HACCP plans, FSIS conducted brief "site reviews" of the volunteer plants, checking layout, facilities, processes, and products, and determining what adaptations of the generic HACCP plans were necessary to make them compatible with specific plant situations. Where necessary, FSIS could reconvene the workshop steering committees to discuss any refinements of the generic HACCP plans, based on the assessment of the generic plans' applicability to the plant's operation. After review of the Refrigerated Foods HACCP model, a change was necessary. Plant-specific HACCP plans were then developed by the volunteer plants. In each pilot plant, the Agency familiarized plant employees and FSIS inspectors with HACCP principles.

FSIS HACCP TEAMS AND EXPERTS

Prior to conducting the HACCP activities, FSIS named subject area experts and formed various teams, to carry out specific HACCP responsibilities. They were as follows:

- Special Team,
- Subject Matter Experts,
- Regional Coordinators,
- Data Collectors,
- HACCP Inspectors,
- Communications Team, and
- Evaluation Team.

Table 3 lists the teams or subject area experts and their responsibilities/activities. For clarity, the narrative of this report will refer to all activities as Agency activities/efforts and generally does refer to any specific team or subject area expert.

TABLE 3: RESPONSIBILITIES OF FSIS HACCP TEAMS AND EXPERTS

Team/Subject Area Expert	Activities
Special Team	Developed generic HACCP model and information notebook for assigned process to increase knowledge level of special team members
	Developed presentation material and workshop manual for HACCP workshops
	Trained/prepared subject matter experts for participation in workshops through one-on-one conversations and in a pre-workshop seminar
	Presented/facilitated at workshops to develop generic HACCP models
	Represented FSIS in soliciting volunteer plants for pilot plant phase of study
	Coordinated steering committee activities to refine workshop generic models
	Prepared instructional/handout material for on-site evaluation in selected pilot plants
	Conducted on-site evaluation
	Assisted plants in writing plant-specific HACCP plans from workshop generic models
	Prepared instructional/handout material and conducted implementation training
	Performed monthly monitoring visits/completed checklist/answered questions
	Represented FSIS in the HACCP study through presentations, distribution of literature, etc., within and outside the Agency
Subject Matter Experts	Communicated with Special Team members to prepare pre-workshop seminars
	Attended pre-workshop seminars and assisted Special Team members in developing a training generic model for the specific workshop process

Team/Subject Area Expert	Activities
	Aided Special Team members in gaining knowledge of specific processes
	Assisted in preparing for the workshops
	Represented FSIS in the workshops
Regional Coordinators	Coordinated workshop logistics, location, facilities, etc.
	Coordinated pre-workshop seminar/arranged for plant tours
	Communicated with subject matter experts
	Assisted in locating volunteer plants for pilot study
	Coordinated announcement for selection of data collectors for pilot plants
	Prepared data collector monitoring plan for specific pilot plants
	Coordinated on-site evaluation logistics
	Attended on-site evaluations
	Trained data collectors
	Communicated with data collectors during all phases of the study
	Coordinated implementation training logistics
	Conducted monthly monitoring visits/completed checklist/answered questions, etc.
	Communicated with HACCP Special Team members and responded to questions relating to the HACCP pilot plants
Data Collectors	Attended on-site evaluation sessions
	Received data collector training
	Collected qualitative/quantitative data during all three phases of the pilot study
	Interacted with pilot plant management/supervisors/employees
	Interacted with pilot plant FSIS inspection personnel
	Answered questions on data collection for FSIS visitors to the plants
	Attended pilot plant implementation training
HACCP Inspectors	Attended on-site evaluation
	Aided plants in understanding HACCP for the completion of the plant-specific HACCP plan
	Interacted with data collectors
	Assisted data collectors, Special Team members, Regional Coordinators in gaining knowledge of pilot plants
	Interacted with FSIS visitors
	Attended implementation training

Team/Subject Area Expert	Activities
	Performed inspection/determined compliance/documented HACCP tasks during implementation and operational phases of the study
	Interacted with plant management relating to the HACCP pilot study
Communication Team	Served as FSIS representative for media at workshops and as needed
	Prepared slides, pamphlets, papers, speeches, news articles, etc., concerning the HACCP pilot study
Evaluation Team	Constructed HACCP assessment plan
	Performed plant visits to complete assessment instruments
	Prepared/captured/analyzed data collectors' information
	Prepared/captured/analyzed HACCP inspectors' information
	Performed analysis and prepared final report

THREE PHASE IN-PLANT PILOT TESTING:
Inspection Personnel:

There were three phases of data collection during the pilot testing of plant-specific HACCP plans. They were Baseline (Phase I), Implementation (Phase II), and Operational (Phase III). During the testing, "data collectors" --FSIS personnel independent of the regularly-assigned inspectors--collected appropriate data on product safety-related factors, to assess the functioning of the plant-specific HACCP plans in operation. FSIS and plant participants agreed that pilot plant identity would not be divulged.

First, FSIS collected baseline data for three months prior to implementing the plant-specific plans. The plants continued to operate as they had in the past. During this period each pilot plant developed its own specific HACCP plan, based on the workshop generic models. Data collectors became familiar with collection procedures. Also, plant employees become accustomed to the presence of extra Agency personnel involved in the pilot testing, reducing what are known as the "Hawthorne effect" and "halo effect." The Hawthorne effect occurs when individuals under study are aware of their "special status" and change their behavior to react "correctly." The halo effect "refers to the tendency for overall positive or negative evaluations of the object or person being rated to influence ratings on specific dimensions (Reference 16).

The second phase of the in-plant pilot study was implementation of plant-specific HACCP plans in three volunteer plants for each product type. This phase lasted approximately three months. Plant personnel adjusted to the new pattern of HACCP controlled operations, found and corrected process control discrepancies, and adjusted the system, where necessary. It was during this phase that plant personnel and Agency

inspectors were trained in HACCP. FSIS shared the baseline and implementation data with plant management.

The third phase began when the Agency and plant management agreed that the plant-specific HACCP system was ready to be operational. This phase lasted six months. FSIS and the pilot plants agreed that data collected during this phase would not be shared with the plant until the final HACCP report.

Tables 4, 5, and 6 show the HACCP. pilot plant schedules by topic area and plants.

TABLE 4: HACCP PILOT PLANT SCHEDULE FOR REFRIGERATED FOODS (RF)

PLANT	DATE	TASK
RF-1	June 11 - 12, 1991	On-site Awareness Training
	July 22, 1991	Start Phase I-Baseline
	January 10, 1992	End Baseline
	January 7 - 9, 1992	Phase II Training
	January 20, 1992	Start Phase II-Implementation
	April 10, 1992	End Phase II
	April 13, 1992	Start Phase III-Operational
	October 9, 1992	End Phase III
RF-2	July 22 - 25, 1991	On-site Awareness Training
	September 9, 1991	Start Phase I-Baseline
	January 24, 1992	End Baseline
	January 14, 1992	Phase II Training
	January 27, 1992	Start Phase II-Implementation
	April 17, 1992	End Phase II
	April 27. 1992	Start Phase III-Operational
	October 16, 1992	End Phase III
RF-3	August 12 - 14, 1991	On-site Awareness Training
	August 18, 1991	Start Phase I-Baseline
	April 17, 1992	End Baseline
	March 24 - 26, 1992	Phase II Training
	April 20, 1992	Start Phase II-Implementation
	September 28, 1992	End Phase II
	October 5, 1992	Start Phase III-Operational
	April 16, 1993	End Phase III

TABLE 5: HACCP PILOT PLANT SCHEDULE FOR COOKED SAUSAGE (CS)

PLANT	DATE	TASK
CS-1	October 15 -17, 1991	On-site Awareness Training
	January 20, 1992	Start Phase I-Baseline
	April 17, 1992	End Baseline
	April 28 - 30, 1992	Phase II Training
	May 4, 1992	Start Phase II-Implementation
	September 11, 1992	End Phase II
	September 14, 1992	Start Phase III-Operational
	March 5, 1993	End Phase III
CS-2	January 21 - 23, 1992	On-site Awareness Training
	February 24, 1992	Start Phase I-Baseline
	October 23, 1992	End Baseline
	October 19 -23, 1992	Phase II Training
	November 2, 1992	Start Phase II-Implementation
	February 19, 1993	End Phase II
	February 22, 1993	Start Phase III-Operational
	August 20, 1993	End Phase III
CS-3	April 20 - 29, 1992	On-site Awareness Training
	June 8, 1992	Start Phase I-Baseline
	September 30, 1992	End Baseline
	October 19 - 23, 1992	Phase II Training
	November 2, 1992	Start Phase II-Implementation
	February 12, 1993	End Phase II
	February 15, 1993	Start Phase III-Operational
	August 13, 1993	End Phase III

TABLE 6: HACCP PILOT PLANT SCHEDULE FOR POULTRY SLAUGHTER (PS)

PLANT	DATE	TASK
PS-1	May 27 - 28, 1992	On-site Awareness Training
	June 1, 1992	Start Phase I-Baseline
	September 18, 1992	End Baseline
	August 24 -28, 1992	Phase II Training
	September 21, 1992	Start Phase II-Implementation
	December 18, 1992	End Phase II
	December 21, 1992	Start Phase III-Operational
	June 18, 1993	End Phase III
PS-2	May 27 - 28, 1992	On-site Awareness Training
	June 1, 1992	Start Phase I-Baseline
	September 4, 1992	End Baseline
	August 24 - 28, 1992	Phase II Training
	September 7, 1992	Start Phase II-Implementation
	December 4, 1992	End Phase II
	December 7, 1992	Start Phase III-Operational
	June 11, 1993	End Phase III
PS-3	May 27 - 28, 1992	On-site Awareness Training
	June 8, 1992	Start Phase I-Baseline
	October 16, 1992	End Baseline
	October 5 - 9, 1992	Phase II Training
	October 18, 1992	Start Phase II-Implementation
	February 26, 1993	End Phase II
	February 28, 1993	Start Phase III-Operational
	August 27, 1993	End Phase III

Plant-Specific Plan:

One of the pilot's purposes was to gain experience in going from generic HACCP plans to plant-specific HACCP plans and processes. The information would assist the Agency in its endeavors to develop a proposed HACCP regulation based on experience rather than theory. In the generic plans, identification of critical control points, requirements for critical limits, monitoring, corrective action, record keeping, and verification were given in broad terms. Each pilot plant developed its own plant-specific HACCP plan, which reflected the individual product, processing, and distribution conditions of that plant. This flexibility allowed the generic plans to be adapted to the unique circumstances of each pilot plant.

Agency In-Plant Activities during Phases I, II and III:

During Phase I, inspection at the plants was conducted as normal, while the plant developed its plant-specific HACCP plan and FSIS collected baseline data. Once the baseline phase was completed, the plant operated its HACCP system for three months during the implementation phase and six months during the operational phase. The Agency utilized the regularly-assigned inspectors throughout the test period, who verified that routine compliance standards were met. Verification was defined as: methods, procedures, and tests used to determine if the HACCP system is in compliance with the HACCP plan. Agency verification tasks were developed from the generic plans.

FSIS inspectors also performed evaluation tasks, which included checking records and looking for trends. Inspectors evaluated records for deviations or deficiencies on scheduled tasks to determine compliance with critical limits identified in the HACCP plan, and with regulatory standards.

The remainder of the chapter discusses the methodological designs used to determine what would be measured, how it would be measured, questionnaire designs, sampling plans and timeframes, and data sources. The order of the discussions is:

1. National Profile Methodology
2. HACCP Model Checklist,
3. Quantitative Plant Data for
    A. Microbiological Factors,
    B. Chemical Factors, and

C. Physical Factors

4. Qualitative Data From Plant Management Assessment for

A. Commitment to control manufacturing process, and

B. Commitment to quality and regulatory compliance

5. Training

A. FSIS

B. Plant

NATIONAL PROFILE METHODOLOGY:

The National Profiles provide a picture of the industry, the three segments (Refrigerated Foods, Cooked Sausage, and Poultry Slaughter), and the nine volunteer plants by various production and inspection characteristics. Various Agency databases were used to develop the National Profiles. These included the Performance Based Inspection System (PBIS), the Special Survey of Refrigerated Foods, and the Animal Disposition Reporting System (ADRS).

The profiles consisted of such characteristics as annual production/slaughter volume, plant square footage (size), and level of compliance to PBIS inspection tasks. PBIS and ADRS data were used to relate health and safety activities for each topic area and to report these data by volume and size characteristics.

PBIS contains the following four major components: Plant profiles (characteristics such as size, volume, and management officials); the Inspection System Guide, a compilation of inspection tasks to measure industry compliance to inspection standards for all processing and allied slaughter activities; a Corrective Action System (procedures for correcting deficiencies); and an automated data support system that schedules inspection activities and records results of FSIS inspections.

FSIS conducted the Special Survey of Refrigerated Foods from September through November 1990 to obtain information on the number of FSIS-inspected refrigerated foods plants and the types of products they produced.

The ADRS uses various forms, one of which is FSIS Form MP-513 (Poultry Inspection--Daily Summary), that include the condemnation rates of slaughtered young chickens.

HACCP MODEL CHECKLIST METHODOLOGY:

Each generic model and each pilot plant's specific HACCP plan were assessed using the 1989 HACCP principles of NACMCF.

The assessment of the generic HACCP plans and plant-specific plans focused on the plans themselves and not on implementation of the plans by the plants. Two checklists of 50 questions (Yes/No) were developed. The checklist for plant-specific plans was expected to have answers to all 50 questions. Generic models, by their very nature, however, did not contain such specificity, and their checklist contained additional scoring category of "not applicable." Each generic model and plant-specific plan was scored against the 50 questions. Each *yes* answer received a positive score of two points (+2). Questions not addressed received a negative score of two (-2). Certain questions required information specific to a plant and its product, which were not likely to be available when the generic model plan was developed. In these cases, the questions were not fully applicable and no score was given. When a question was partially addressed, a positive score of one (+1) was awarded. The minimum conformance level to the principles outlined by the NACMCF was +50 points.

QUANTITATIVE PLANT DATA METHODOLOGIES:

Quantitative methodologies were developed to assess microbiological, chemical, and physical factors. For each of the three areas, FSIS identified specific factors, developed sampling plans, assigned analytical test procedures, and designed survey instruments. The Agency also gave specific instructions for collecting, mailing, and receiving samples, and for following laboratory protocols. A survey questionnaire was designed for the physical factors. The factors were identified without reference to the HACCP models because the models were not developed at the time the study design and plan were completed. The factors were selected based on their relation to health and safety and once the HACCP models were developed, further assessment was made as to the appropriateness of testing for each factor at a specific critical point.

Selection of Microbial Organisms:

Microbial sampling and testing were conducted to provide information about a food manufacturer's process. For this purpose, a wide range of microbial tests was selected to recover pathogenic and non-pathogenic microorganisms capable of growing in both the product and the environment under varying conditions.

The eight microbiology factors were:

1. Aerobic Plate Count @35°C,
2. Aerobic Plate Count @20°C,
3. Coliforms,

4. *Escherichia coli* (Biotype I),
5. *Staphylococcus aureus*,
6. Gas Forming Anaerobes,
7. *Salmonella* species.
8. *Listeria* species,

All the factors except *Salmonella* were selected to assess the processes in refrigerated and cooked sausage plants. Listeria was selected to assess the processing environment. In poultry slaughter plants, *Salmonella* was added as a microbiology factor, and *Listeria* and APC @ 20°C were not included.

Brief Description of Microbiology Factors:

A discussion of the choice of organisms to be used in microbiological criteria is found in the National Academy of Sciences (NAS) study, "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients" (Reference 17). The rationale used in that book was incorporated into the FSIS HACCP study.

Aerobic Plate Count @35°C: A count of total aerobic microorganisms present in a sample and indicative of the bioburden present. The count will be lowest just after effective cooking, but will increase with time as the surviving microorganisms grow and multiply. The rate of multiplication increases when the storage temperature rises.

Aerobic Plate Count @20°C: Similar to the definition above, but the lower temperature of incubation favors growth of psychrotrophic (cold tolerant) spoilage organisms over those which might cause human illness. Very high APC @20°C counts (>10,000,000 CFU/g) indicate that product is approaching the end of its useful shelf-life. This will ultimately occur with all perishable food products stored under refrigeration.

Coliforms: Coliform bacteria, normally present in meat, poultry, and many other raw food products, are readily destroyed during heat processing. Excessively high coliform counts may result from massive contamination, process failure, or from extended processing delays, or from improper storage temperature (time-temperature abuse).

Escherichia coli: This coliform species are associated with warm blooded animals, including humans, includes both pathogenic and non-pathogenic biotypes and is relatively heat sensitive. The presence of *E. coli* in a heat-processed food indicates underprocessing and/or postprocessing contamination through equipment or utensils, by persons handling the cooked food, or from cross-contamination with raw foods. Occasionally, a few *E. coli* organisms

reach the final product, even under reasonably good manufacturing practices.

Staphylococcus aureus: The presence of *S. aureus* in food indicates direct or indirect contamination from human or animal sources. Foodborne illness is the result of the ingestion of the enterotoxin produced when *S. aureus* reach high levels (> 10^5 cells/g). The enterotoxin is not destroyed by heating.

Gas Forming Anaerobes: Gas-Forming Anaerobes (GFAs) include spore-forming *Clostridia*, such as *Clostridium perfringens*. Adequate heat treatment destroys the vegetative *Clostridia* in meat, but spores may survive. If meats containing these spores are held at temperatures between 68 and 122°F, the spores may grow and multiply, creating a potential health hazard. High levels of GFAs in a cooked product generally indicate improper cooling or prolonged temperature abuse.

Listeria species: Some species of the genus *Listeria*, which includes the pathogenic species *Listeria monocytogenes* and several non-pathogenic species, can grow and multiply at refrigeration temperatures, making this an excellent indicator of the effectiveness of cleaning and sanitization procedures in processing environments.

Salmonella species: High levels of *Salmonella* in raw products immediately after slaughter may be indicative of improper cooling, temperature abuse, or ineffective scalding, evisceration, or washing. Microbiological testing for *Salmonella* was performed only in the poultry slaughter plants.

Microbiology Analytical Methods:

The analytical methods used for the various microbiology factors are described in FSIS's Microbiology Laboratory Guidebook Section 3 (1974), (Reference 18) with the following modifications:

1. Substitution of 3M™ petri film for enumeration of coliforms, *E.coli* and APC.

2. *Salmonella* analytical method as described in Food Technology, 1969, 23:80-85 (Reference 19) and section 4, MLG as modified by the substitution of DMLIA plating media Journal of Food Protection, 1988, 51:391-396 (Reference 20).

Chemical Factors Methodologies:

The chemical factors in the pilot testing were not used as indicators of chemical hazards, but rather, to supplement the microbial testing and evaluate any observed microbial changes.

Chemistry sampling and testing were conducted for the cooked sausage plants and poultry slaughter plants. The chemistry testing methodology called for performing the following tests on applicable product by topic area.

Chemistry Factors for:

Refrigerated Foods

Chemistry sampling was not done at the three refrigerated foods plants because their products were not amenable to the selected chemistry factors.

Cooked Sausage

Nitrites: Cooked sausages are allowed by regulation to contain a restricted amount of sodium or potassium nitrite. The use of nitrites at a level not to exceed 156 ppm (parts per million) provides a barrier in the formulation of the product in addition to refrigeration, against the growth of certain microorganisms. Excessive amounts of these curing materials are toxic.

Salt (Brine): Moisture and salt concentrations were determined so that the brine content could be calculated. The brine content is the concentration of salt in the aqueous fraction of the product. It is calculated by dividing the amount of salt by the amount of salt plus moisture. The brine content of a product relates to the water activity of the product, which, in turn, influences the extent of microbial growth possible in the product.

Poultry Slaughter

Chlorine in Processing Water: Chlorinated water is used to reduce the level of microorganisms in carcass chillers and in reprocessing procedures. Chlorine test kits were used to verify the concentration of chlorine in the wash or spray water.

Chemistry Analytical Methods:

Type II protein content was determined by the Kjedahl method, moisture by the Forced Draft Oven Method, and salt by the Volhard Procedure. Brine was determined, by calculation, from salt and moisture values. Nitrite was determined by a modification of the Griss Method. The percentage of nitrite in each new batch of curing material was also checked by laboratory analysis. For poultry slaughter facilities, tests of the concentration of total chlorine in processing water were performed in-plant, by an inspector using a HACH model CN-21P test kit, which FSIS had evaluated and found to be sufficiently accurate within the expected working range.

SAMPLING PLANS:

The sampling plan called for collecting sample sets for both microbiology and chemistry on 30 to 50 different days during the baseline, implementation, and operational phases. Samples were analyzed at the FSIS's Mid-Western Laboratory.

The microbiological results from Phase I were shared with these plants at the beginning of Phase II and those from Phase II were shared as they became available. Phase III began when both the Agency and plant management agreed that the HACCP system had been fully implemented. Due to a five-to six-week lag time between sample collection and feedback, the microbiology and chemical results were of little use to plant management for process control decisions. However, the shared results were useful for verification tasks performed by FSIS personnel. The Phase III results were shared with the plants when the case study reports were completed.

Microbiological Sampling Plan:

The samples were taken at selected locations during processing for the baseline (Phase I), implementation (Phase II), and operational (Phase III) phases of the study. Samples were to be frozen and then shipped to the FSIS's Mid-Western Laboratory.

For refrigerated foods plants, samples were collected for the first six microbial factors at three points in the production process: 1) before cooking; 2) after cooking and chilling; and 3) the final packaged products. Cooked sausage plant samples were collected for the first six microbial factors at three points: 1) after stuffing, but before cooking; 2) after cooking and chilling; and 3) the final packaged product. All sampling locations were chosen to provide information before and after processing steps which are known to influence the microbiological condition of the final product.

Listeria species testing was performed on four different equipment surfaces on an alternating basis. Swabs for *Listeria* were taken and reported as positive or negative, but were not quantified.

Salmonella testing was performed only in the poultry slaughter area at four different locations: just prior to entry into the scald tank; from the transfer table after hock cutting; after the final washer and just prior to the chill tank; and after the final chill tank.

Table 7 displays the original microbiological sampling plan, by product type and phase. The plan was to collect sample sets on 30 to 50 different days during both the baseline and operational phases. The actual number of samples collected is shown in Table 8.

TABLE 7: MICROBIOLOGICAL SAMPLING PLAN BY PRODUCT TYPE AND PHASE

PRODUCT TYPE	TOTAL NUMBER OF SAMPLES TARGETED*	
	PHASE I BASELINE	PHASE III OPERATIONAL
Refrigerated Foods Plants	550	550
Cooked Sausage Plants	600	600
Poultry Slaughter Plants	600	600
Total	1750	1750

* Sampling Targeted for 30 to 50 days with minimum samples per point set at 30 per phase.

TABLE 8: NUMBER OF MICROBIOLOGICAL SAMPLES COLLECTED BY PRODUCT TYPE, PLANT, AND PHASE

PRODUCT TYPE/PLANT	ACTUAL NUMBER OF SAMPLES COLLECTED	
	PHASE I BASELINE	PHASE III OPERATIONAL
Refrigerated Foods		
Plant 1	372	192
Plant 2	209	123
Plant 3	239	106
Total	820	421
Cook Sausages		
Plant 1	200	142
Plant 2	203	183
Plant 3	291	129
Total	694	454
Poultry Slaughter		
Plant 1	228	208
Plant 2	212	204
Plant 3	264	200
Total	704	612

Chemistry Sampling Plan:

In cooked sausage plants, samples were collected for nitrites and salt testing. Final product samples were collected for nitrites and salt. In addition, samples of curing mixtures were collected for nitrite testing.

For poultry slaughter, sampling of total chlorine in water was done daily with the water being sampled as it entered the chiller.

Inspectors were instructed to alternate morning and afternoon collection. However, collection was more typically carried out at various times during a single shift, since testing was generally done by the same inspector.

Table 9 displays the number of chemistry samples collected for the product type by plant.

TABLE 9: NUMBER OF CHEMISTRY SAMPLES COLLECTED BY PRODUCT TYPE, AREA, PLANT, AND PHASE

PRODUCT TYPE/PLANT	NUMBER OF SAMPLES COLLECTED	
	PHASE I	PHASE III
Refrigerated Foods - NA*		
Cooked Sausage		
Plant 1	58	38
Plant 2	75	14
Plant 3	74	48
Total	207	100
Poultry Slaughter		
Plant 1	68	117
Plant 2	65	121
Plant 3	43	71
Total	176	309

* The three plants' products were not amenable to proposed refrigerated food chemistry testing.

PHYSICAL FACTORS METHODOLOGY:

The term "physical factor" in this study refers to product attributes or processing characteristics that have an effect on the final product wholesomeness or safety. The term should not be considered synonymous with "physical hazards" as defined by HACCP. The physical factors identified for study purposes were developed prior to the availability of the generic HACCP models and were intended to provide a broad overview of the plant's controls and operations.

Physical factors are process control oriented. For example, the temperature of a product at receiving, or the presence of foreign material in a product during processing, are product attributes that affect the wholesomeness of a final product. The temperature of a storage area or the accuracy of a thermometer are processing characteristics that affect the wholesomeness of a final product.

Observations made of a plant's efforts to control physical factors, such as temperature and presence of foreign material, give an indication of a plant's control of its manufacturing processes. Plant control of each physical factor was assessed through direct observation by a FSIS data collector prior to HACCP implementation (Baseline Phase I) and after HACCP implementation (Operational Phase III) to determine if plant controls changed.

FSIS constructed a series of data collection tasks for each product type (Refrigerated Foods, Cooked Sausage, and Poultry Slaughter) to assess plant control of physical factors. Each series of data collection tasks contained several sets of questions. Plant control of physical factors was assessed by observing plant monitoring activities, plant records, and plant reactions to process deviations.

Verification tasks at each physical factor were conducted by the data collector to ascertain the effectiveness of plant control. For example, temperature and organoleptic wholesomeness of product at receiving was identified as a physical factor that assures acceptable product is brought into the plant. The data collector would observe the plant actions at receiving to determine if an established procedure is followed when incoming product is brought into the plant. Secondly, the data collector observed if the plant documented the findings when an assessment of incoming product was made. Thirdly, the data collector determined if proper corrective action were taken when unwholesome product was received or was received at too high a temperature. Lastly, the data collector verified that product received was in fact wholesome and at proper temperatures by conducting their own temperature checks and wholesomeness checks.

Physical Factors:

The physical factors for refrigerated foods, cooked sausage, and poultry slaughter are displayed in Table 10. A brief description of the purpose of each factor by product type follows. Both refrigerated foods and cooked sausage plants had the same five factors, while

poultry slaughter had three factors. The factors for each product type are as follows:

Refrigerated Foods and Cooked Sausages:

The physical indicators for Refrigerated Foods and Cooked Sausages are:

Temperature - Maintenance of proper temperature minimizes undesirable microbial growth.

Organoleptic Wholesomeness/Foreign Material - Organoleptic signs of spoilage (such as: odor, slipperiness) or contamination are indications of unacceptable product, while foreign materials (metal, glass, etc.) are potential hazards.

Heat Treatment/Internal Temperature/Cooling Treatment - Application of appropriate heat increases shelf-life and decreases the number of microorganisms; inadequate heat treatment allows microorganisms to survive. After cooking or heating, product must be cooled to a specified temperature in an appropriate amount of time.

Cross-Contamination - Prevention of cross-contamination of cooked products by contact with raw products.

Packaging - Package integrity deters microbiological proliferation and finished product date coding allows for the removal of unsafe product.

Poultry Slaughter:

The three poultry slaughter physical factors were:

Sanitation - Preventing contamination in slaughter facilities and on equipment at pre-operational sanitation and mid-shift cleanup; determining the level of sanitation of automatic eviscerating machinery and potential of cross-contamination; and determining the accuracy of sanitary controls in removing slaughter/processing debris from equipment, utensils, and structures.

Contamination - Preventing fecal contamination and cross-contamination of product and equipment from carcasses leaking feces; effective manufacturing process for controlling visible contamination on carcasses going into the chiller; and effective plant salvage and reprocessing procedures.

Product Handling - Preventing condemned materials from being used as human foods; assessing the accuracy of inspection helpers who respond to inspection instructions; assessing sanitary practices of salvage and reprocessed products; and determining the

efficiency of product flow and time and temperature conformance.

TABLE 10: PHYSICAL FACTORS FOR REFRIGERATED FOODS, COOKED SAUSAGE AND POULTRY SLAUGHTER VOLUNTEER PLANTS

REFRIGERATED FOODS	COOKED SAUSAGE	POULTRY SLAUGHTER
1. Temperature	1. Temperature	1. Sanitation
2. Foreign Material/ Organoleptic Wholesomeness	2. Foreign Material/ Organoleptic Wholesomeness	2. Contamination
3. Time/Temperature	3. Time/Temperature	3. Product Handling
4. Cross-Contamination	4. Cross-Contamination	
5. Packaging	5. Packaging	

Questionnaire Design

All data collection instruments were pretested, and necessary changes were made in wording, scaling, or ordering. Correlation meetings were held with the data collectors, who were thoroughly trained in using the instruments so as to ensure consistency in findings.

Each set of questions in the data collection questionnaire was designed to measure whether the plant 1) followed an established procedure (plant monitoring); 2) documented findings (plant records); and 3) took corrective action (plant response to process deviations).

For example, to measure the plant's control of the foreign material and organoleptic wholesomeness of raw meat received, the following data collection questions were used:

1. Does plant **follow established procedures** in performing wholesomeness checks on incoming meat/poultry raw materials?

2. Does plant **document** its findings on incoming meat/poultry raw materials?

3. Does plant **take action** when incoming meat/poultry raw materials do not meet specifications?

The Agency conducted ***verification*** testing. This testing was done using a fourth question in the set of data collection tasks, called the verification task. This task measured actual adherence by the plant to the control point's requirements.

For example, to measure ***verification*** of the control point *foreign material/organoleptic wholesomeness of raw meat received,* the fourth question in the data collection task read:

> *4. Select five units of meat/poultry raw materials at receiving and determine if wholesome.*

The data collection questions were applied in Phase I (Baseline) and again in Phase III (Operational) to assess plant control and Agency verification before and after HACCP implementation.

Data collection task and frequency:

Prior to the study, computer modeling was conducted to simulate scheduling of data collection tasks in the pilot plants. The modeling was based on task time allocations developed by FSIS' Industrial Engineering and Ergonomics Staff and assigned frequencies of three times per week for the scheduled tasks. As a result of the modeling, task frequencies were adjusted to fit inspection resource allocations.

The frequency for the scheduled task that measured adherence to established procedures was set at three times per week. This provided a target number of 39 observations over the planned 13-week study. The frequency for the scheduled verification task was set at three times per week. Assuming a 13-week study, this would produce 39 observations.

QUALITATIVE DATA:

Qualitative data were collected from plant records, plant personnel and inspection operations personnel to provide a perspective on plant management's commitment to process control, quality, regulatory compliance, and HACCP. This information was gathered using various survey questionnaires. Data were also collected to assess how well the training of Agency and plant personnel assisted them in transitioning into a HACCP work environment. survey/questionnaire/data collection instruments. The instruments were designed and pretested at various plants using Agency headquarters' staff as data collectors.

Due to resource constraints, the number of plants enlisted into the study as well as the on-site reviews conducted was limited, which made it possible for the data to be biased by day-to-day operational variability. The Agency took significant steps to prevent these biases, including extensive pretesting of the various instruments, training of data collectors, and holding correlation sessions with the data collectors to discuss the issues, concerns, and ambiguities that might arise from the instrument design, wording, scaling, and scoring.

The remainder of this section discusses the objectives and designs for the following qualitative areas:

1. Management commitment to manufacturing processes, quality, and regulatory compliance, and

2. Industry and Agency Training.

Plant Management: Manufacturing Processes and Quality and Regulatory Compliance Commitments Methodology:

In an effort to understand the possible effects of HACCP on meat and poultry plant's operating environment, eleven qualitative factors were identified as providing an overview of the processing or slaughter plant environment and provide a qualitative assessment of the overall level of regulatory compliance of the nine pilot plants. The factors were designed to measure plant management's commitment, willingness, and capabilities for controlling the manufacturing process; and the plant management's attitudes toward and commitment to producing quality and regulatory compliance-based product, especially in areas that impact consumer health and safety.

FSIS identified 11 qualitative categories which are displayed in Table 11. The questionnaire was designed, pretested, and modified following correlations with the data collectors. Besides having specific criteria for each of the major categories, data collectors also gave narrative descriptions. The most significant modification to the questionnaire was the expansion of the ordinal rating scales (Likert-type scale) from three levels to five. The original high, medium, and low categories were expanded and defined as follows:

1. High - a factor that greatly exceeds regulatory requirements;

2. High medium - a factor that meets regulatory requirements with some additional effort to exceed regulatory requirements;

3. Medium medium - a factor that completely meets regulatory requirements;

4. Low medium - a factor that just barely meets the minimum regulatory requirements; and

5. Low - a factor that does not meet regulatory requirements.

TABLE 11: QUALITATIVE CATEGORIES FOR PLANT MANAGEMENT: Manufacturing Processes and Quality and Regulatory Compliance Commitments Methodology

ITEM NO.	QUALITATIVE FACTORS
1.	General Housekeeping
2.	Condition of facilities
3.	Employee hygiene
4.	Employee sanitary practices
5.	Employee attitudes toward inspection requirements
6.	Employee training
7.	Management supervisory attitudes
8.	Management response to problems
9.	Management strategies to prevent contamination hazards
10.	Product quality
11.	Management programs and systems

The original medium category was expanded after results of field testing the questionnaire showed most plant factors at that level. It was thought that, after implementation of HACCP, many of these factors might show improvement, but still qualify only for a medium rating. The expanded scale was adopted to distinguish a high medium from a low medium.

Industry and Agency Training:

At the outset of the HACCP initiative, FSIS recognized that training was essential to the study's success. A review of HACCP literature revealed that a thorough understanding of HACCP principles, concepts, and techniques is necessary for individuals who develop HACCP plans, or monitor and verify a plan's operation. This includes both food processors and regulatory personnel. A basic understanding of HACCP principles is important for food handlers and others working in food production, as well as an understanding of the importance of their individual functions within the HACCP plan.

The objective of the HACCP training that FSIS conducted at the participating plants was to familiarize both plant and inspection personnel with HACCP principles. The Agency sought to give plant personnel sufficient understanding to begin developing their plant-specific HACCP plans. Plants were encouraged to provide additional in-depth training to employees responsible for developing and managing the HACCP plans.

The training took place at the participating plants (or local training sites) just before Phase II of the HACCP study. The primary audience for this training was inspection personnel assigned to the participating plants. Since neither the data collector training nor the initial awareness training was assessed, these activities are not addressed in this report.

The HACCP training was conducted by Agency employees who had helped the plants develop their specific HACCP plans and who were liaisons with the plant throughout the study. Each training session lasted three days. The topics included: an overview of the HACCP pilot study, specific in-depth discussion of the seven HACCP principles, the conversion from generic models to plant-specific HACCP plans, and in-depth instruction on the operation of the PBIS as modified for the HACCP plants. Training methods included lecture, discussion, and hands-on workshops to demonstrate practical applications of HACCP and PBIS.

The training was assessed to determine how well it functioned, to gain insights on the training needs of inspectors working in a HACCP-based inspection system, to gain insights on the content needed in HACCP training, to begin consideration of the target population for HACCP training, and to learn about the best formats for delivering such a training program.

The immediate aim of the training assessment was to provide feedback to the Agency to improve future training sessions by assessing the HACCP training needs of FSIS inspection personnel and gauging the effectiveness of the delivery method.

Data Collection:

The data collection methodology used in the training assessment consisted of: 1) direct observation of FSIS training of its employees and industry personnel at training sites; 2) administration of a reaction survey questionnaire to trainees immediately after training; 3) observation of FSIS employees' performances during Phase II (implementation) and Phase III (operational) of the pilots; 4) informal interviews with FSIS employees; and 5) review of the training materials.

Agency evaluators observed one training session from each of the product/process categories. Evaluators' attendance at training sessions was scheduled so that each pair of FSIS trainers could be observed leading a session. Evaluators reviewed lesson plans, visual aids, and other materials to determine their usefulness in meeting the training objectives. Participants at all training sessions were asked to fill out an evaluation sheet. Participants included FSIS personnel (inspectors, relief inspectors, circuit supervisors, area officials, regional officials, and

HACCP data collectors) and plant personnel, plant managers, production supervisors, and quality control/quality assurance staff. All data to assess the training were forwarded to FSIS headquarters for analysis.

CHAPTER III

ANALYSIS FOR REFRIGERATED FOODS, COOKED SAUSAGES AND POULTRY SLAUGHTER HACCP SYSTEMS PILOT TESTING AT NINE VOLUNTEER PLANTS

INTRODUCTION:

Detailed discussions and analyses of pilot test results of plant-specific HACCP plans for Refrigerated Foods, Cooked Sausages, and Poultry Slaughter at nine volunteer plants will be presented for National Profiles, HACCP Model Checklist, Quantitative Plant Data, and Qualitative Data. To keep the confidentiality of the participating plants' identities, they will be identified as 1, 2, or 3 for their respective product areas (i.e., RF 1, RF 2, RF 3; CS 1, CS 2, CS 3; PS 1, PS 2 and PS 3).

NATIONAL PROFILES: IDENTIFYING REFRIGERATED FOODS PLANTS, COOKED SAUSAGE PLANTS, AND POULTRY SLAUGHTER PLANTS.

To present an overview of the general plant population from which the plants volunteered, FSIS collected and analyzed information from all meat and poultry plants producing ready-to-eat refrigerated foods, cooked sausages, and young chickens (poultry slaughter). The 1992 profile data were collected from the Agency's Performance Based Inspection System (PBIS) and Animal Disposition Reporting System (ADRS) data bases to determine the general characteristics of plants by size (as measured by square feet of plant space) and production volume.

USDA Plant Population:

FSIS inspects approximately 6,200 meat and poultry establishments (see Table 12). Over 1,600 are processing plants only, while there were less than 400 slaughter plants, and more than 1,300 combination plants (a plant that slaughters and performs processing is a combination plant/establishment).

TABLE 12: NUMBER AND TYPE OF PLANTS UNDER FEDERAL INSPECTION

TYPE	NUMBER
Processing	4,557
Slaughter	378
Combination	1,345
TOTAL	6,280

By reviewing PBIS and other plant survey data, FSIS identified 322 Refrigerated Food plants and 1,004 Cooked Sausage plants for study.[1] Using the ADRS data base, FSIS identified 225 poultry plants that slaughtered young chickens.

Table 13 identifies plants as Processing, Red Meat Slaughter, and Poultry Slaughter Operations. When performing the profile analysis, it is important to differentiate between a plant/establishment and the operations a plant conducts. A plant may perform multiple types of operations. The term **operations** refers to the number of different species slaughtered or processing operations being performed by a plant. A slaughter plant may slaughter beef and swine or chicken and turkey. A processing plant may produce cooked sausages and a ready-to-eat refrigerated food product. Processing represents nearly two thirds of all federally-inspected plants, while poultry slaughter represents five percent (See Chart 1). Table 14 shows that the Refrigerated Foods plants are around seven percent (322 plants) and Cooked Sausage plants about 16 percent (1,004 plants) of the 6,253 processing operations (See Chart 2).

TABLE 13: NUMBER OF FEDERALLY-INSPECTED OPERATIONS FOR PROCESSING, RED MEAT SLAUGHTER AND POULTRY SLAUGHTER

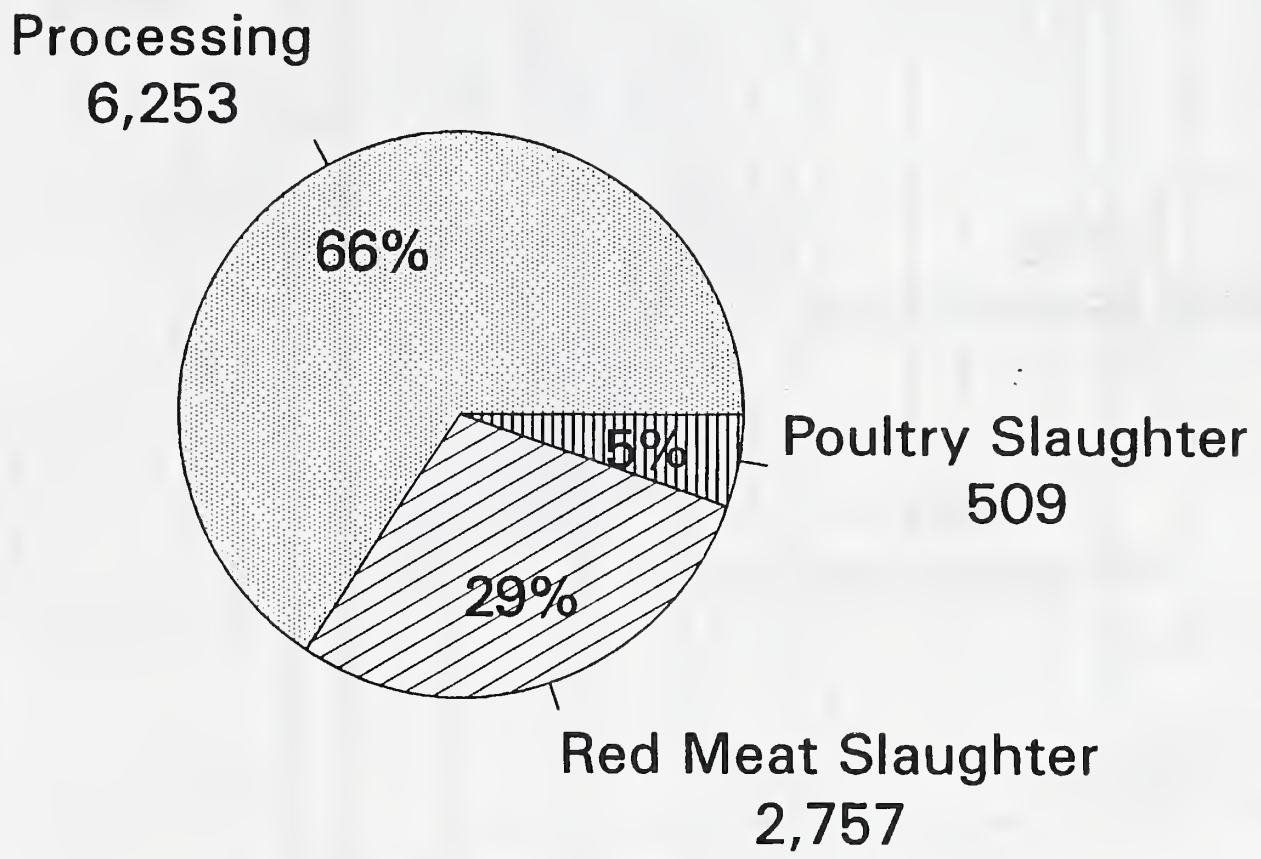
TYPE OF PLANT	NUMBER	PERCENT OF TOTAL
PROCESSING	6,253	65.75
RED MEAT SLAUGHTER	2,757	29.0
POULTRY SLAUGHTER	509	5.3
TOTAL	9,519	100.0

[1] Plant number reporting PBIS data may vary due to multiple shifts.

Chart 1

NUMBER OF FEDERALLY INSPECTED FSIS OPERATIONS

December, 1992



Note: Actual plant numbers are lower since a plant may conduct multiple operations

Chart 2

NUMBER OF PROCESSING PLANT OPREATIONS

6,253 total

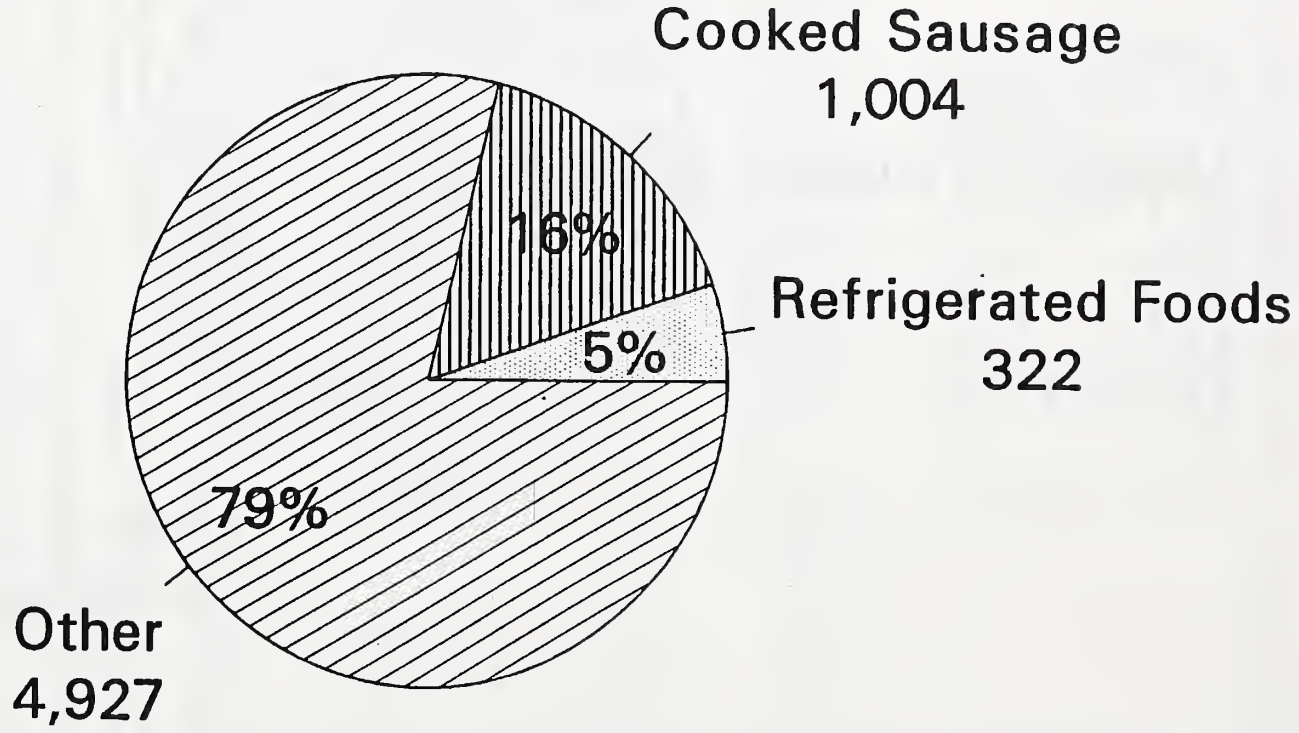


TABLE 14: POPULATION OF PROCESSING OPERATIONS BY REFRIGERATED FOODS, COOKED SAUSAGES AND ALL OTHERS

PROCESSING PLANTS (in-plant numbers)		PERCENT OF TOTAL
REFRIGERATED FOODS	322	6.9
COOKED SAUSAGE	1,004	16.0
OTHER	4,821	77.1
TOTAL	6,253	100.0

Table 15 displays the composition of Red Meat Slaughter and Poultry Slaughter operations. Of the 2,757 Red Meat Slaughter operations (see Chart 3), Beef Slaughter represents approximately two in every five operations (37.3 percent) while Swine Slaughter is around one in every three operations (34.2 percent). For Poultry Slaughter (See Chart 4), Chicken Slaughter dominates, representing nearly three in every five operations (59.5 percent).

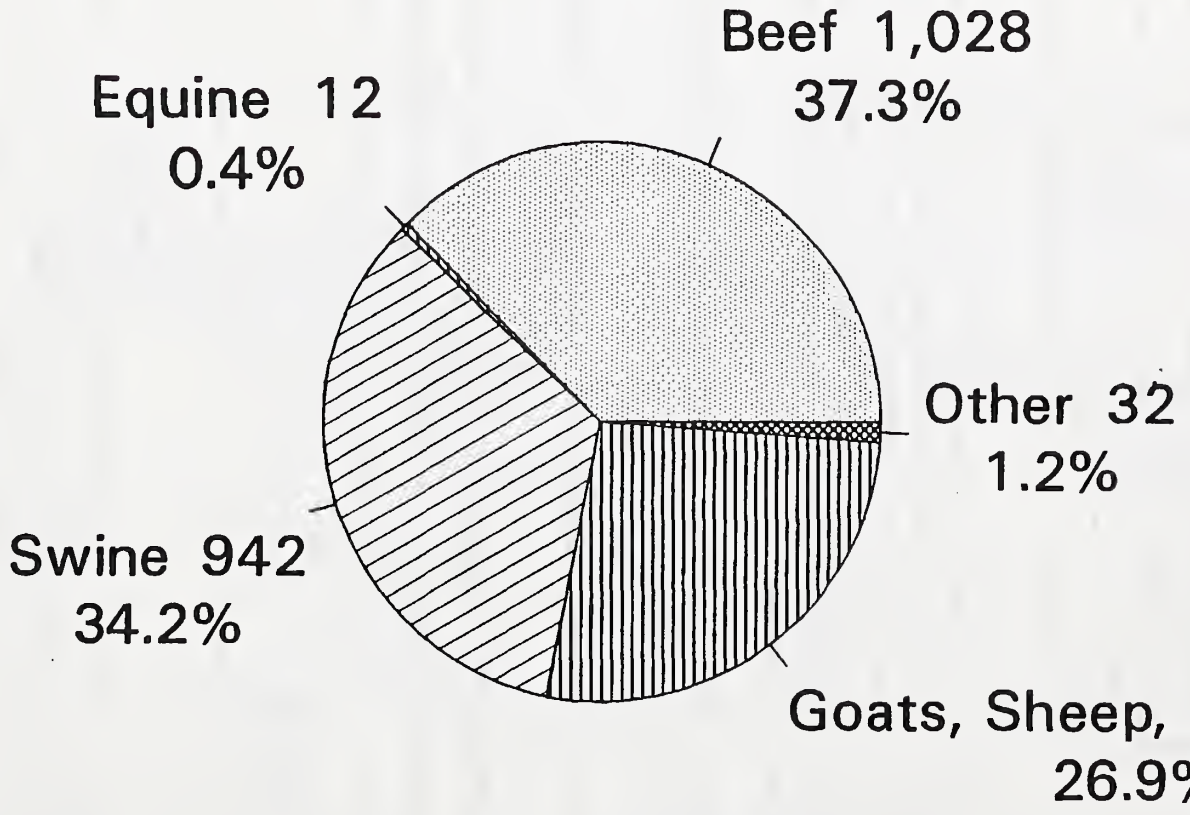
TABLE 15: RED MEAT AND POULTRY SLAUGHTER PLANTS BY SPECIFIC SPECIES COMPOSITION

SLAUGHTER PLANTS					
Red Meat		Percent of Total	Poultry		Percent of Total
Beef	1,028	37.3	Chicken	303	59.5
Swine	942	34.2	Turkey	156	30.6
Goats, Sheep, Lamb	743	26.9	Ducks	26	5.1
Equine	12	0.4	Geese	9	1.8
Other	32	1.16	Rabbits	4	0.8
			Others (guineas, squab, pigeons)	11	2.2
Total*	2,757		Total*	509	

* Total compounded thus does not represent absolute number of plants. For example, one plant may slaughter both beef and swine.

Chart 3

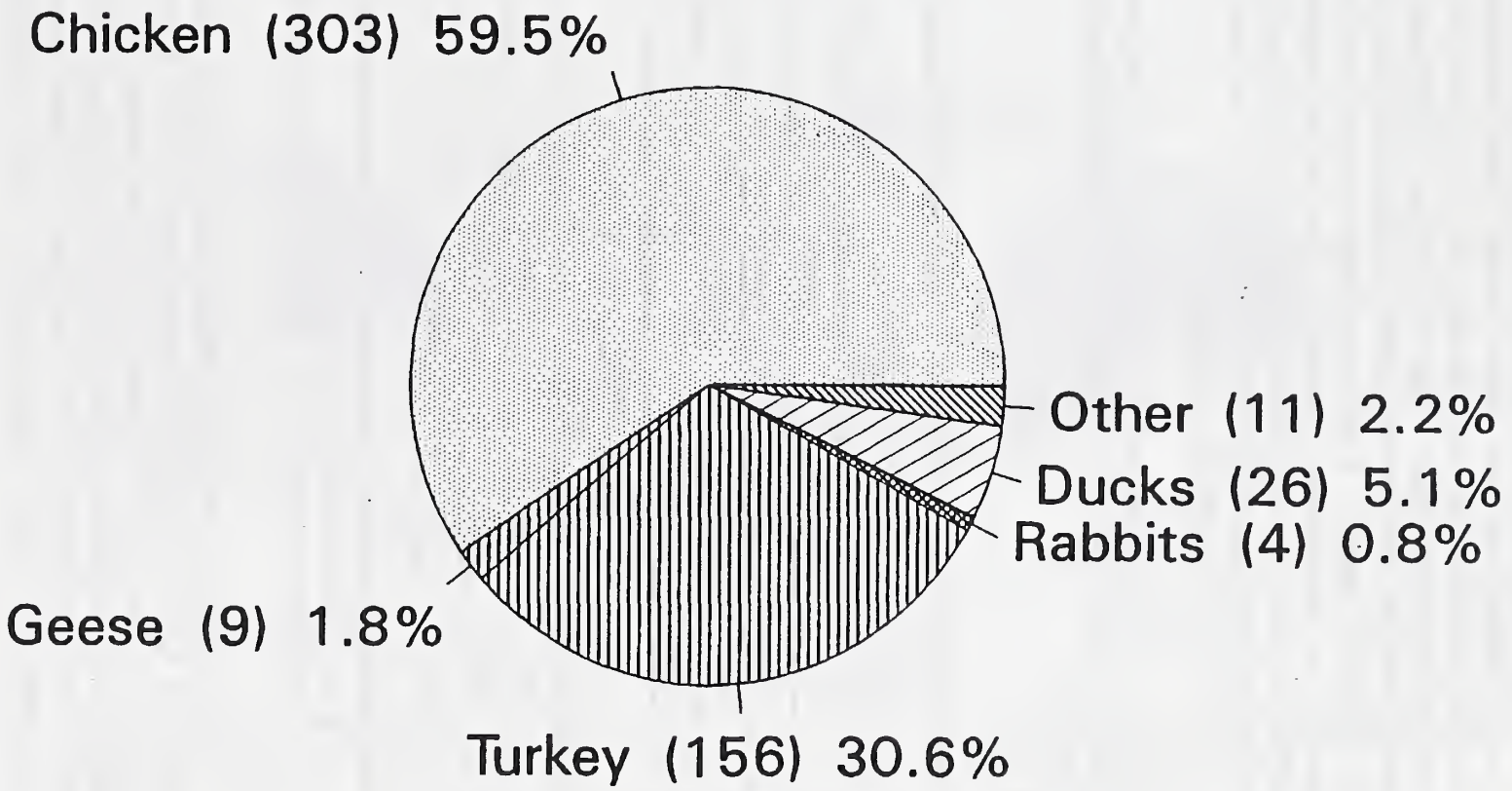
NUMBER AND PERCENTAGE OF RED MEAT SLAUGHTER OPERATIONS BY SPECIES



Total Operations = 2,757
Total Plants = 1,541

Chart 4

NUMBER AND PERCENTAGE OF POULTRY SLAUGHTER PLANT OPERATIONS



Total Operations = 509
Total Plants = 320

Characteristics used to profile processing operations were: plant volume (pounds produced annually) and size (square footage). Table 16 displays the distribution of processing operations by square footage. Of the 6,253 processing operations, 41 percent were medium volume plants (producing between 240,000 and 4,000,000 pounds of product annually [See Chart 5]), while 33 percent were high volume producers (more than 4,000,000 pounds). Low volume producers (less than 240,000 pounds annually) represent one in every four (26 percent). With respect to square footage, small plants (having less than 12,000 square feed of plant area) dominated; 64 percent of all processing plants were small. Nine percent of the plants were classified as large (i.e., more than 80,000 square feet of plant area.

TABLE 16: CLASSIFICATIONS FOR PRODUCTION AND SQUARE FOOTAGE INTERVALS WITH THE NUMBER AND PERCENTAGE OF PLANTS IN EACH INTERVAL

Category	Interval	Number of Plants	Percent of Total
Annual Volume in Pounds	Pounds		
Low	< 240,000	1,605	26
Medium	240,000 - 4,000,000	2,570	41
High	> 4,000,000	2,078	33
Total*		6,253	100
	Interval		
Square Footage**	Square Feet		
Small	< 12,000	3,901	64
Medium	12,000 - 80,000	1,639	27
Large	> 80,000	547	9
Total		6,087	100

* Production of Official Establishment (POOE) Data for 1992

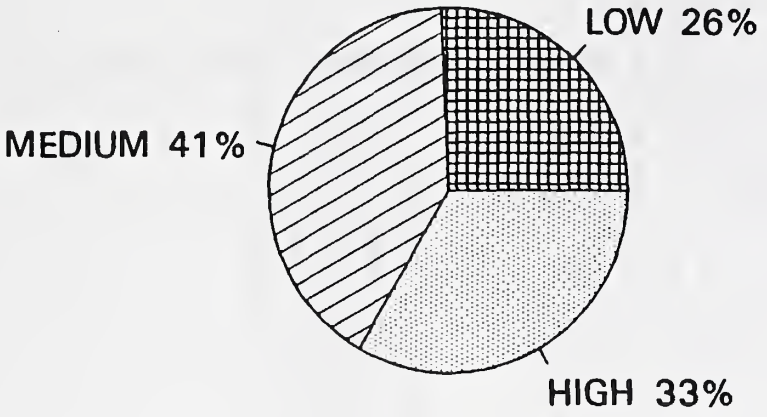
** Square footage data is reported by CORE. Data were not reported for 166 establishments.

The Production of Official Establishment (POOE) data represents the annual volume reported by 5,411 of the 6,253 processing plants in 1992. Chart 6 shows that high volume producers (i.e. over 4,000,000 pounds annually) accounted for 95 percent of the 64.7 billion pounds, with average annual production for the 1,355 plants reporting being nearly 44 million pounds. The total volume of 1,704 small volume producers represented 1 percent of the total annual production, with the average annual production of a small plant being nearly 357,000

Chart 5

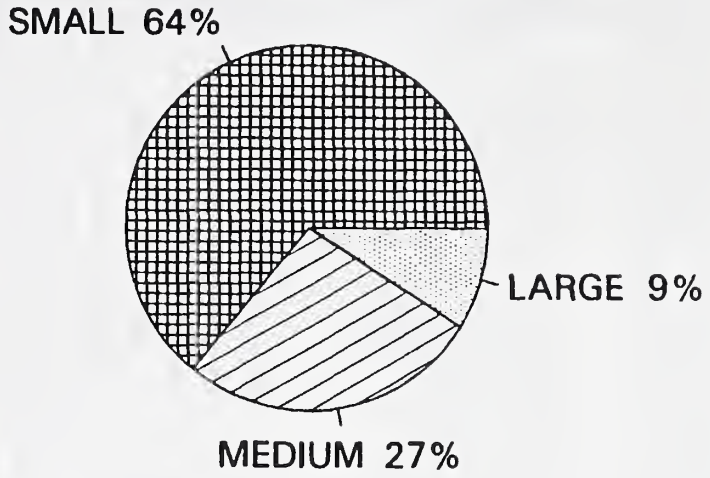
PROCESSING PLANTS

by plant size and production volume



VOLUME

LOW < 60,000 lbs quarterly
MEDIUM 60,000 - 1,000,000
HIGH > 1,000,000



SIZE

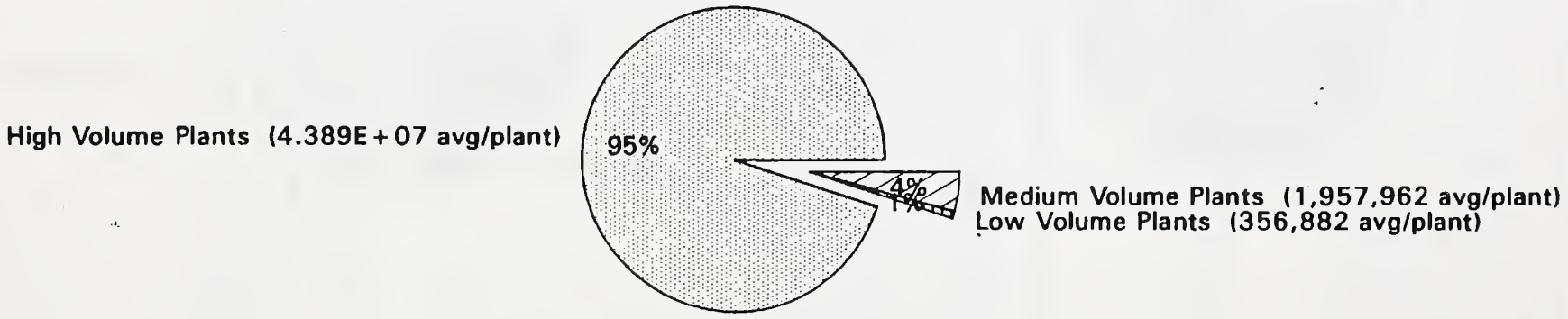
SMALL < 12,000 sq.ft. inspected area
MEDIUM 12,000-80,000
LARGE > 80,000

6,253 Plants Total

Chart 6

PRODUCTION VOLUME OF PROCESSED PRODUCTS

December, 1992



Total Annual Production of Processed Products
64.6 billion pounds

5,411 of 6,253 Plants Reporting

pounds. Chart 7, which portrays the Refrigerated Foods, Cooked Sausage, and all other processing plant data, shows that Cooked Sausage plants (16.2 percent of the plants) represented about 20 percent of the annual production.

For Red Meat and Poultry Slaughter, the item of interest is the number of head or birds slaughtered annually. Table 17 displays the red meat total slaughter and poultry slaughter figures. In 1992 nearly 7 billion animals were slaughtered. The poultry slaughter represented nearly 6.9 billion birds. Chicken slaughter represents nearly 95 percent of all poultry slaughter. Red meat slaughter accounted for nearly 127 million head in 1992.

Refrigerated Foods Plants:

Examination of the Refrigerated Foods plant population for the volume characteristic, Chart 8 indicated a distribution similar to the general plant population (see Chart 5). However, when using the criterion of size (i.e., square footage), only half of the Refrigerated Foods plants are in the small range, compared to 64 percent of all plants. Nearly three in every eight Refrigerated Foods plants (38 percent) were classified as medium in size, versus a little over one in four (27 percent) for the general plant population. The category of large size plants showed about the same for the Refrigerated Foods plants as for the general plant population (11 percent and 9 percent, respectively). All three volunteer plants were high volume producers; there was one plant in each size category.

Cooked Sausage Plants:

As seen in Charts 5 and 9, comparing Cooked Sausage plants to the general plant population shows more Cooked Sausage plants in the medium category for annual production volume than the general population (47 percent and 41 percent, respectively) with the shift coming from a lower percentage of high volume producers (28 percent and 33 percent, respectively). When looking at plant size, the Cooked Sausage plants are similar to the general population. There is a slight shift in the percentage of medium sized firms, with the difference coming from a lower percentage of small plants in the Cooked Sausage plants (59 percent, compared to 64 percent for the general population). The cooked sausage plants' annual production volumes classified CS 1 and CS 3 as high volume plants.

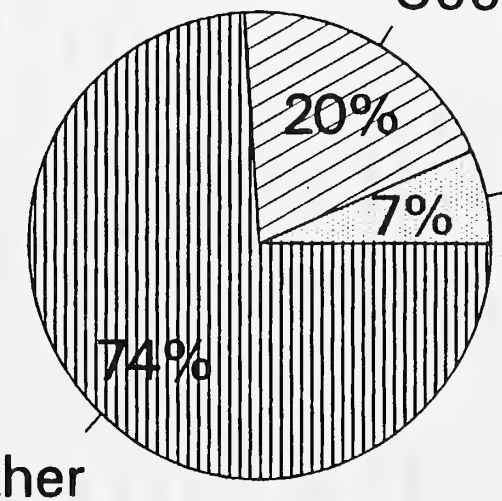
Poultry Slaughter Plants:

For Fiscal Year 1992, ADRS data showed that more than 6.852 billion poultry were slaughtered (see Table 17) at 320 poultry slaughter plants. Young chickens were slaughtered in 225 of the plants (70.3 percent of the 320 plants) and dominated the total poultry slaughter volume, with more than 6.368 billion birds (92.9 percent). Table 17 shows the classification, number, and percentage of poultry plants in each category, as well as the percentage of total poultry slaughter volume.

Chart 7

PRODUCTION VOLUME OF PROCESSED PRODUCTS

By Cooked Sausage, Refrigerated Foods, and all other plants



Cooked Sausage
12.6 Billion lbs

Refrigerated Foods
4.2 Million lbs

All Other
47.8 Billion lbs

Total Annual Production of Processed Products
64.6 billion pounds

5,411 of 6,250 Plants Reporting
December, 1992

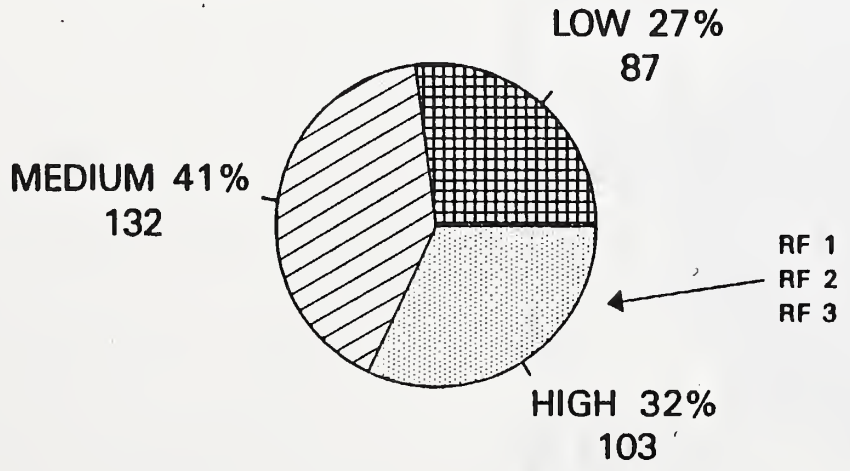
TABLE 17: RED MEAT AND POULTRY SLAUGHTER BY CLASS FOR USDA INSPECTED SLAUGHTER PLANT OPERATIONS - FY '92

Class	Head Slaughtered	Percent of Slaughter	Number of Operations	Percent of the 2757 Plants
Red Meat				
Cattle	32,112,363	25.3	1028	37.3
Swine	89,210,132	70.3	942	34.2
Sheep/Goat	5,354,043	4.2	743	26.9
Other Red Meat	247,273	0.2	44	1.6
Total	126,923,811	100		
Class	**Head Slaughtered**	**Percent of Slaughter**	**Number of Plants**	**Percent of the 320 Plants**
Young Chickens	6,368,360,156	92.9%	225	70.3%
Light Fowl	129,530,164	1.99%	38	11.9%
Fryer-Roaster Turkeys	1,403,436	0.02%	4	3.4%
Young Turkeys	274,092,153	4.0%	10	28.1%
Old Breeder Turkeys	2,394,944	0.0%	34	10.6%
Ducks	18,027,590	0.0%	26	2.8%
Geese	161,449	0.0%	44	2.8%
Rabbits	431,975	0.0%	44	1.3%
Others (Guineas, Squabs etc.)	4,442,675	0.0%	10	3.4%
Capons	288,729	0.0%	10	3.1%
Heavy Fowl	51,309,759	0.7%	30	9.4%
Young Breeder Turkeys	1,709,070	0.0%	28	8.8%
Total	6,852,152,100	100.0%		

Chart 8

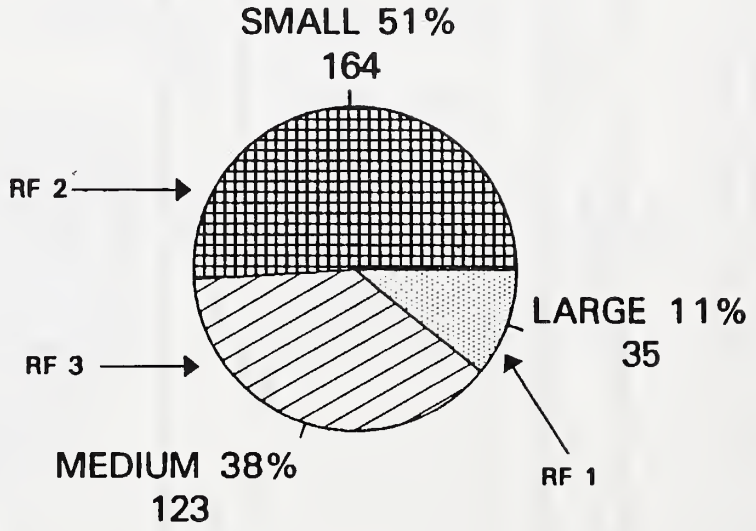
REFRIGERATED FOODS PLANT PROFILE

by Production Volume and Plant Size



VOLUME

LOW <60,000 lbs quarterly
MEDIUM 60,000 - 1,000,000
HIGH > 1,000,000



SIZE

SMALL <12,000 sq.ft. inspected area
MEDIUM 12,000-80,000
LARGE >80,000

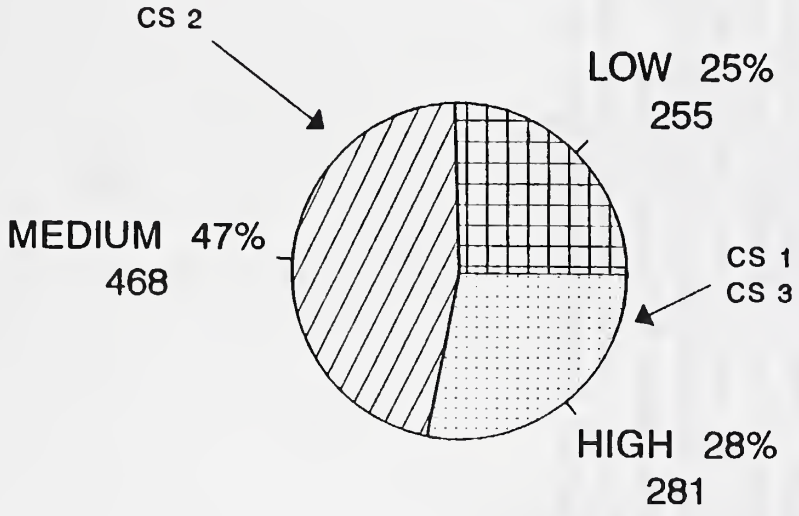
322 Plants Total

December, 1992

Chart 9

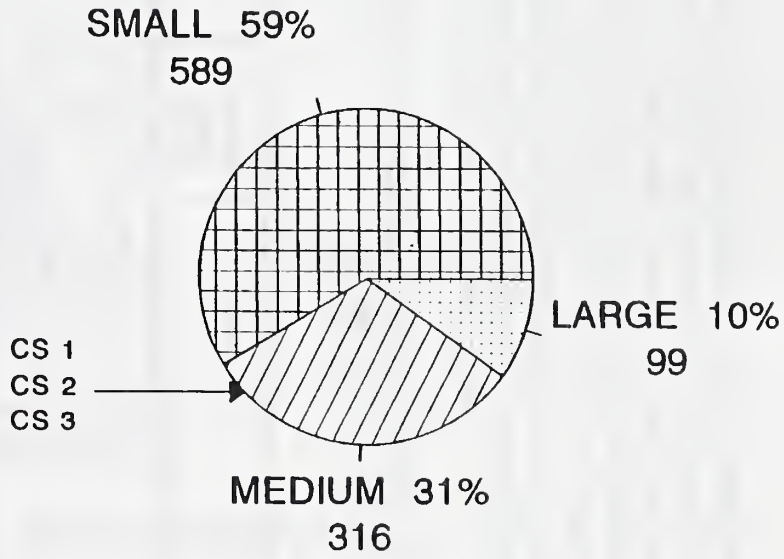
COOKED SAUSAGE PLANT PROFILE

by Production Volume and Plant Size



VOLUME

LOW <60,000 lbs quarterly
MEDIUM 60,000-1,000,000
HIGH >1,000,000



SIZE

SMALL <12,000 sq.ft. inspected area
MEDIUM 12,000-80,000
LARGE >80,000

1,004 Plants Total

December, 1992

Table 18 presents the same classifications for young chicken slaughter. Low volume slaughterers (less than 10 million) represented almost 30 percent of the plants, but less than 2 percent of the total birds slaughtered, while the high volume producers (more than 50 million birds) represented approximately 15 percent of the plants, but nearly 35 percent of the slaughter volume. PS 1 and PS 3 were high volume slaughter plants, while PS 2 was a medium volume plant. Chart 10 presents the poultry slaughter data by low, medium, and high volume classifications. The average annual slaughter for low, medium, and high volume producers was 1.5, 31.6, and 86.0 million birds, respectively.

TABLE 18: CLASSIFICATION AND NUMBER VOLUME OF YOUNG CHICKEN SLAUGHTER PLANTS - FY '92

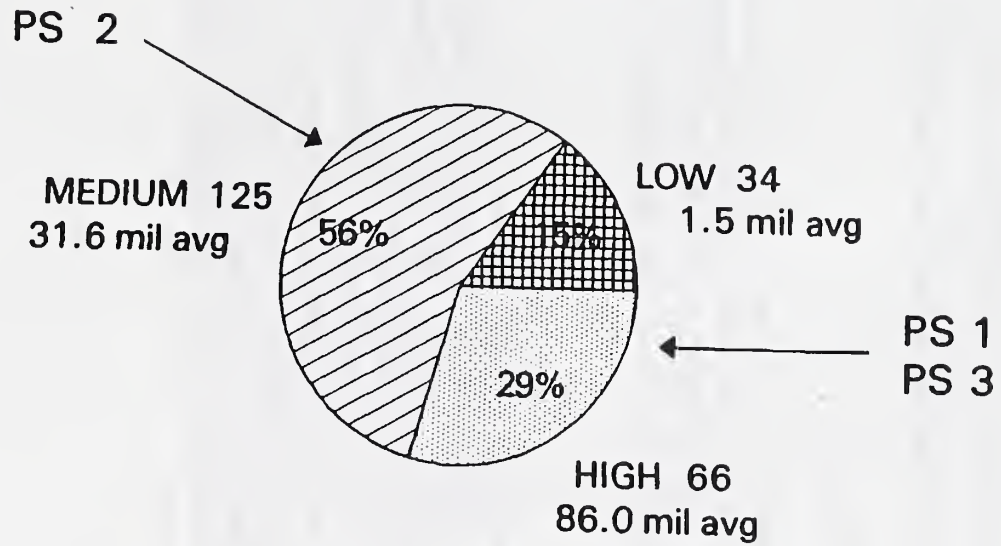
Classification	Range	Number of Plants	% of Plants	% of Young Chickens Slaughtered
Low	< 10,000,000	66	29.3	1.8
Medium	10,000,001 - 50,000,000	125	55.6	63.5
High	> 50,000,000	34	15.1	34.7
Total		225	100.0	100.0

Table 19 displays the number of young chickens slaughtered, number of condemned chickens, and the condemnation rate at all young chicken slaughter operations, PS 1, PS 2, and PS 3. FY 92 ADRS data showed 6.4 billion young chickens were slaughtered at 225 young chicken slaughter operations. The average slaughter was 28.3 million young chickens per plant. All three plants (PS 1, PS 2, and PS 3) were above the average. PS 2 slaughtered over 30 million while PS 1 and PS 3 slaughtered 76.7 and 62.1 million, respectively. The total number of young chickens condemned in FY 1992 was 61,548,308 which translates into a national condemnation rate of 0.97 percent. As seen in Table 19, PS 1, PS 2, and PS 3 rates were 1.08 percent, 0.81 percent, and 0.52 percent, respectively. PS 1 (1.08 percent) was slightly above the national rate (0.97 percent), while PS 3 (0.52) was almost half of the national rate.

Chart 10

YOUNG CHICKEN PLANT VOLUME

December, 1992



PLANT VOLUME (225 total plants)
6,368,360,156 total slaughtered

HIGH > 50,000,000 birds processed annually
MEDIUM 10,00,000 - 50,000,000
LOW < 10,000,000

TABLE 19: NUMBER OF YOUNG CHICKENS CONDEMNED AND CONDEMNATION RATE FOR PS 1, PS 2, AND PS 3

PLANT	NUMBER SLAUGHTER	NUMBER CONDEMNED	PERCENT OF TOTAL
PS-1	76,714,340	824,942	1.08
PS-2	30,303,122	244,313	0.81
PS-3	62,086,896	824,942	0.52
ALL PLANTS	6,368,360,156	61,548,308	0.97

HACCP MODEL CHECKLIST

This section discusses the conformance of the nine plant-specific plans and the three generic model HACCP plans to the seven principles recommended by the NACMCF. More detail on the checklist methodology appears in Chapter 2. Table 20 shows the summary of the scoring and point deductions for all nine volunteer plant plans.

Refrigerated Foods:

Of the 50 questions in the checklist, the generic Refrigerated Foods HACCP Plan addressed 38, with 12 found to be not applicable (see Table 21). The Refrigerated Foods HACCP model was found to be in 100 percent conformance with the NACMCF recommendations. All three Refrigerated Foods plants' specific plans addressed all 50 questions. RF 3 was in 98 percent conformance with NACMCF recommendations, while RF 1's and RF 2's plans were each in 97 percent conformance. None of the three Refrigerated Foods plants' plans adequately addressed (i.e., specifically listed) the microbiological hazards for the Hazard Assessment area in the checklist, as shown in Table 20. Additionally, none of their plans fully addressed the basis for the frequency of monitoring under establishment of monitoring requirements.

TABLE 20: HACCP MODEL CHECKLIST SCORING SUMMARY AND POINT DEDUCTIONS FOR THE REFRIGERATED FOODS, COOKED SAUSAGES, AND POULTRY SLAUGHTER VOLUNTEER PLANTS

PLAN		POSSIBLE POINTS	POINTS DEDUCTED	QUESTIONS NOT FULLY ADDRESSED*					
RF	MODEL	100	0						
	1	100	3	B5	E2	E4			
	2	100	3	B5	E2	E4			
	3	100	2	B5	E2				
CS	MODEL	100	1				H3		
	1	100	2		E2	E4			
	2	100	2		E2	E4			
	3	100	0						
PS	MODEL	100	2					E6	H4b
	1	100	2		E2	E4			
	2	100	2					E6	H4b
	3	100	2					E6	H4b
TOTALS		1200	21	3	6	5	1	3	3

TABLE 21: CHECKLIST RESPONSE TOTALS AND SCORING SUMMARY FOR REFRIGERATED FOODS HACCP MODEL PLANS

Summary of responses to questions:

PLAN	TOTAL NUMBER OF QUESTIONS	NUMBER ADDRESSED IN PLAN	NUMBER NOT ADDRESSED IN PLAN	NUMBER NOT FULLY APPLICABLE
WORKSHOP MODEL	50	38	0	12
PLANT NUMBER 1	50	50	0	0
PLANT NUMBER 2	50	50	0	0
PLANT NUMBER 3	50	50	0	0

Summary of scores:

PLAN	TOTAL POSSIBLE SCORE	SCORE OF "YES" RESPONSES	SCORE OF "NO" RESPONSES	SCORE OF "NOT FULLY APPLICABLE " RESPONSES	PERCENT CONFORMANCE TO NACMCF RECOMMENDATIONS
WORKSHOP MODEL	100	77	0	23	100%
PLANT NUMBER 1	100	97	0	0	97%
PLANT NUMBER 2	100	97	0	0	97%
PLANT NUMBER 3	100	98	0	0	98%

Cooked Sausage:

Table 22 presents the summary of responses and scores for the Cooked Sausage topic plants, while Table 20 includes the scoring and point deductions. As with the Refrigerated Foods generic HACCP plan, the Cooked Sausage Generic HACCP plan addressed 38 out of the 50 questions, with 12 found to be not applicable.

However, the Cooked Sausage generic plan did not receive a 100 percent score because it did not address the frequency of verification inspection. CS 3's plan fully conformed to the NACMCF recommendations, for a score of 100 percent. CS 1's and CS 2's plans scored 98 percent; neither plan addressed the frequency of monitoring nor included the documentation relative to the effectiveness of established cooking, cooling, etc., procedures.

TABLE 22: CHECKLIST RESPONSE TOTALS AND SCORING SUMMARY FOR COOKED SAUSAGE HACCP MODEL PLANS

Summary of responses to questions:

PLAN	TOTAL NUMBER OF QUESTIONS	NUMBER ADDRESSED IN PLAN	NUMBER NOT ADDRESSED IN PLAN	NUMBER NOT FULLY APPLICABLE
WORKSHOP MODEL	50	38	0	12
PLANT NUMBER 1	50	50	0	0
PLANT NUMBER 2	50	50	0	0
PLANT NUMBER 3	50	50	0	0

Summary of scores:

PLAN	TOTAL POSSIBLE SCORE	SCORE OF "YES" RESPONSES	SCORE OF "NO" RESPONSES	SCORE OF "NOT FULLY APPLICABLE " RESPONSES	PERCENT CONFORMANCE TO NACMCF RECOMMENDATIONS
WORKSHOP MODEL	100	76	0	23	99%
PLANT NUMBER 1	100	98	0	0	98%
PLANT NUMBER 2	100	98	0	0	98%
PLANT NUMBER 3	100	100	0	0	100%

Poultry Slaughter:

The checklist response totals and scoring summary for Poultry Slaughter are displayed in Table 23; while the scoring and point deductions appear in Table 20. The Poultry Slaughter HACCP generic plan addressed 38 questions, with 12 found not to be fully applicable. The overall score for the generic plan was 98 percent because two questions were not fully addressed. The Poultry Slaughter generic plan did not specifically state the need for designating responsible individuals and their signatures for the monitoring data. It also failed to specifically state the need for designating responsible individuals and their signatures for CCP monitoring.

PS 1's plant-specific plan showed deficiencies similar to those of RF 2 and RF 3 and CS 1 and CS 2. PS 1's plan did not specifically address the need for designating responsible individuals and signatures for monitoring data or the frequency of collection. PS 2's and PS 3's plans showed the same deficiency as the generic Poultry Slaughter plan by not designating

responsible individuals and their signatures for CCP monitoring. Neither PS 2's nor PS 3's plans specifically mentioned the need for designating individuals and their signatures for monitoring data.

TABLE 23: CHECKLIST RESPONSE TOTALS AND SCORING SUMMARY CHECKLIST FOR POULTRY SLAUGHTER HACCP MODEL PLANS

Summary of responses to questions:

PLAN	TOTAL NUMBER OF QUESTIONS	NUMBER ADDRESSED IN PLAN	NUMBER NOT ADDRESSED IN PLAN	NUMBER NOT FULLY APPLICABLE
WORKSHOP MODEL	50	38	0	12
PLANT NUMBER 1	50	50	0	0
PLANT NUMBER 2	50	50	0	0
PLANT NUMBER 3	50	50	0	0

Summary of scores:

PLAN	TOTAL POSSIBLE SCORE	SCORE OF "YES" RESPONSES	SCORE OF "NO" RESPONSES	SCORE OF "NOT FULLY APPLICABLE " RESPONSES	PERCENT CONFORMANCE TO NACMCF RECOMMENDATIONS
WORKSHOP MODEL	100	75	0	23	98%
PLANT NUMBER 1	100	98	0	0	98%
PLANT NUMBER 2	100	98	0	0	98%
PLANT NUMBER 3	100	98	0	0	98%

In summary, the major deficiencies revealed by the HACCP model checklist were that six of the nine plant's plans lacked specificity in their monitoring requirement procedures for continuous monitoring, or the plans did not specifically state the statistical based frequency of the non-continuous monitoring requirements, while five of the nine plans (two Refrigerated Foods, two Cooked Sausage and one Poultry Slaughter) did not specifically mention the need for designating responsible individuals and their signatures for monitoring data.

ANALYSIS OF MICROBIOLOGICAL, CHEMICAL, AND PHYSICAL QUANTITATIVE DATA:

As discussed under Methodology, Chapter 2, testing for microbiological chemical, and physical factors was conducted to ascertain the degree of process control that each of the nine volunteer plants exercised. Since chemistry factors were used to assess how microbial growth was affected, the analyses of microbiological and chemistry factors will be discussed together for each of the three product types. This section will first discuss the results of the baseline and operational phases (Phases I and III) testing for the microbiological and chemical factors, and then the results of the physical factors testing. Chapter 2 (Methodology) provides a discussion on the statistical methods used for analyzing the microbiological data.

Microbiological and Chemical Factors Analyses:

Refrigerated Foods Plants:

The quantitative data for the three volunteer Refrigerated Foods plants included seven microbiology factors and no chemistry factors. The seven microbiology factors are listed in Chapter II.

Samples were collected for the first six of these factors at three different points in processing: (1) before cooking; (2) after cooking and chilling; and (3) from final packaged product. Results for these factors were reported in counts per gram. Swabs for *Listeria* species tests were taken from four different equipment surfaces on an alternating basis. Results for *Listeria* tests were reported as simply positive or negative (not quantified).

The sampling sites were purposely selected to bracket critical control points in the production of refrigerated foods. These critical control points are those related to cooking, chilling, and post-cooking handling of the product. The cooking process is the only critical control point in the production of this product where an appreciable reduction of microbial levels can be expected. The sampling sites are depicted in Tables 24, 26 and 28 in relation to both the critical control points and other steps in the production process. The mean microbiological levels for each of the microbiological factors at each of the sampling sites are shown in the same tables. The values in the tables for points prior to cooking show the microbiological condition of the raw material. The values immediately after cooking and chilling indicate the effectiveness of the cooking process in reducing microbial levels and the effectiveness of the chilling process in retarding multiplication of any survivors. The final values in the tables indicate the degree of sanitation practiced during the steps of the process resulting in the final packaged product. In these tables, as indicated in the notes under the tables, a value of one was assigned to samples which were negative to facilitate the calculation of the geometric mean.

Tables 25, 27 and 29 present the percent of samples testing positive for each of the microbiological factors and the log average level for each.

The plan to collect sample sets on 30 to 50 different days during both the baseline and operational phases (Phases I and III) was fulfilled for two of the three Refrigerated Foods plants and nearly fulfilled in the other plant (only 27 daily samples were collected during Phase III in that plant). The results were analyzed to check each plant's ability to control its process and to compare characteristics of product produced in Phases I and III. Results are discussed separately for each plant.

Results for microbiology factors from Phase I were shared with the plants at the beginning of Phase II, and results from Phase II were shared as they became available. Because of the 5-to-6 week lag between sample collection and feedback of results, the data were not useful for monitoring process control, but were of retrospective value for assessment purposes.

In summary, the HACCP microbiological factors in RF 1 showed little, if any, practical difference between Phase I and Phase III microbiologically. The microbiological profile of product produced during both phases is indicative of good manufacturing procedures.

Refrigerated Foods plant 1 (RF 1):

Table 24 shows geometric means for the six quantitative microbiology factors at the different sampling points for RF 1 during Phases I and III. It relates the sampling points to the generic HACCP Refrigerated Foods model and demonstrates the change in the microbial profile during the process. As seen in the table, the microbiological levels of incoming raw material were low. The cooking process further reduced the levels of microorganisms -- in many cases, to below the level of detection. The levels of microorganisms in the final product were slightly higher, reflecting post-cooking handling of the product; however, the overall microbiological profile of the final product in both Phase I and Phase III is indicative of excellent processing procedures. Because of these low levels, there is no practical difference between the microbial profiles of product sampled during Phase I and product sampled during Phase III.

Table 25 gives more detailed summary statistics for the microbiology factors at the three sampling points during Phases I and III. There are a greater number of samples for final product because duplicate final product samples were collected each sampling day in this plant. Only APC @ 35°C and APC @ 20°C showed appreciable percent positives in the final product (see Pct values). Figures 1 and 2 show the distribution of APC @ 35 and 20°C respectively for RF 1. As seen, the values drop significantly from the raw product process to final product both in Phase I and Phase III. The slight increase in samples testing positive

TABLE 24: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III REFRIGERATED FOODS PLANT 1

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
	1,280	2,730	22	1	3	2
	1,880	3,640	23	1	2	5
Cooking*						
Chilling*						
	1	1	1	1	1	1
	1	1	1	1	1	1
Assembly*						
Flush (Gas)*						
Seal Package						
Inspect Package*						
Labeling, etc.*						
Chilling*						
	2	2	1	1	1	1
	2	1	1	1	1	1
Storage*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

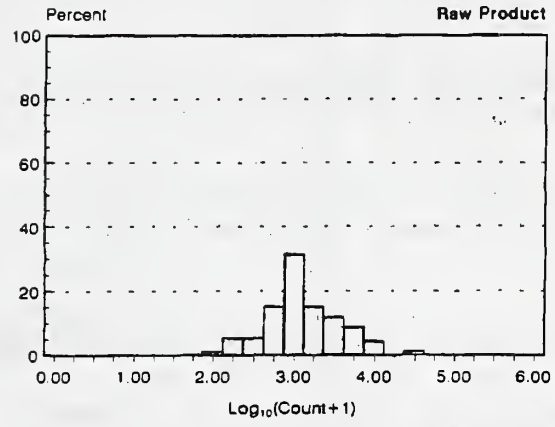
TABLE 25: SUMMARY STATISTICS FOR MICROBIAL FACTORS REFRIGERATED FOODS PLANT 1

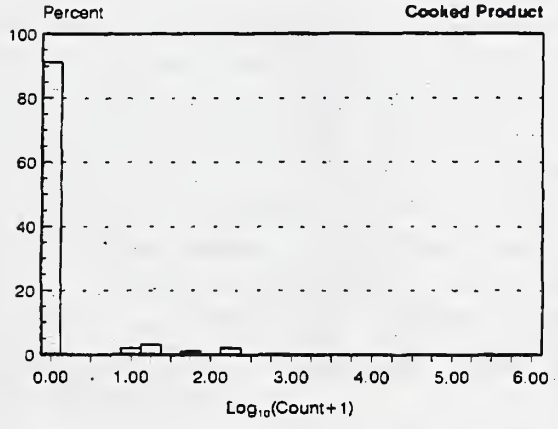
Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	92	100.0	3.1	.46	92	8.7	1.5	.54	188	17.6	1.7	.64
	3	48	100.0	3.3	.43	48	4.2	1.5	.67	96	14.6	1.6	.54
APC @20°C	1	92	100.0	3.4	.62	92	4.3	1.8	.19	188	19.1	1.1	.56
	3	48	100.0	3.6	.62	48	2.1	1.7		96	10.4	0.0	.64
Coliforms	1	92	76.1	1.8	.48	92	1.1	.19		188	1.1	1.0	.00
	3	48	79.2	1.7	.52	48	0.0			96	0.0		
E. coli	1	92	6.5	1.3	.40	92	0.0			188	0.0		
	3	48	12.5	1.0	.00	48	0.0			96	0.0		
S. aureus	1	92	21.7	2.4	.54	92	0.0			188	0.0		
	3	48	10.4	2.1	.21	48	0.0			96	0.0		
GFAs	1	92	27.2	1.1	.41	92	0.0			188	0.5	1.0	
	3	48	50.0	0.0	.56	48	0.0			96	0.0		

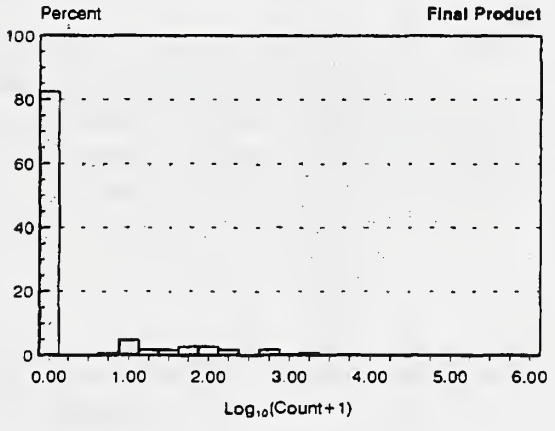
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

Figure 1. APC@35°C Distributions - Plant RF1

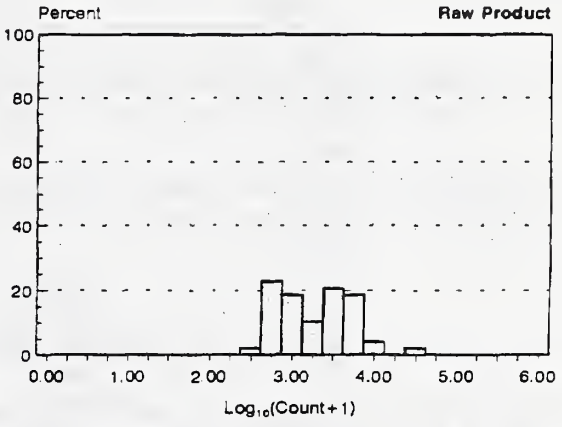
Phase 1

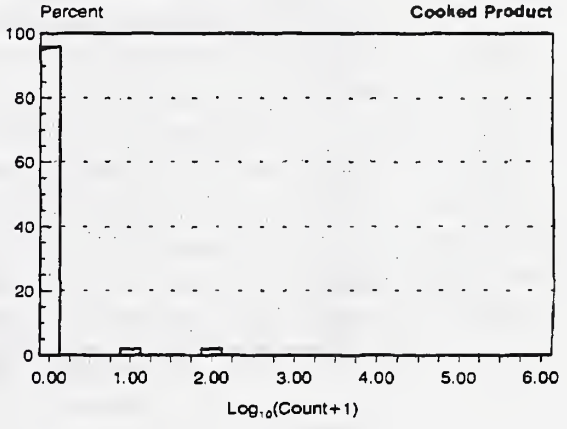






Phase 3





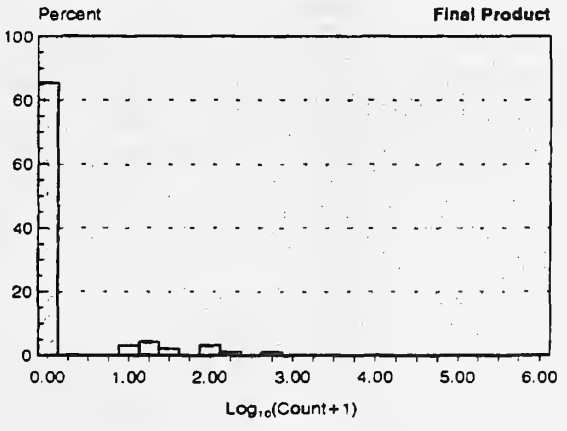
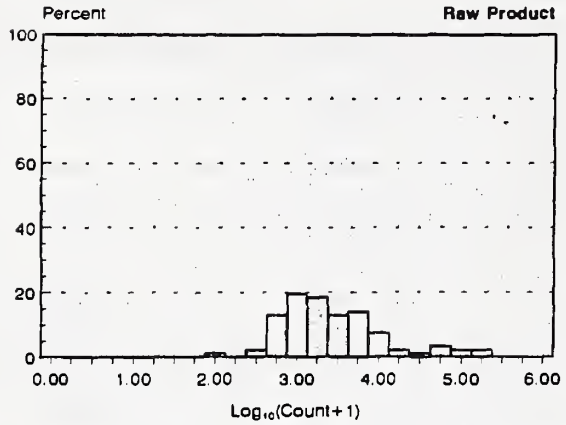
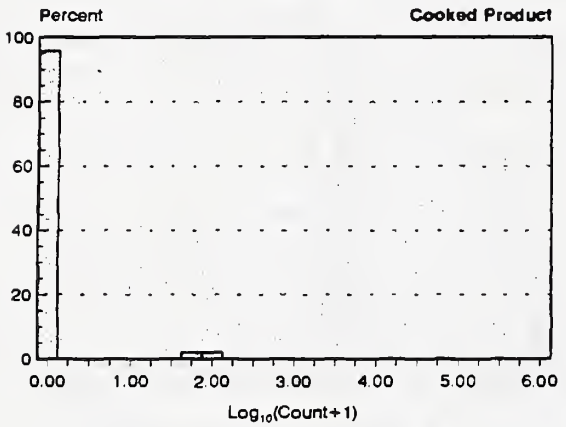
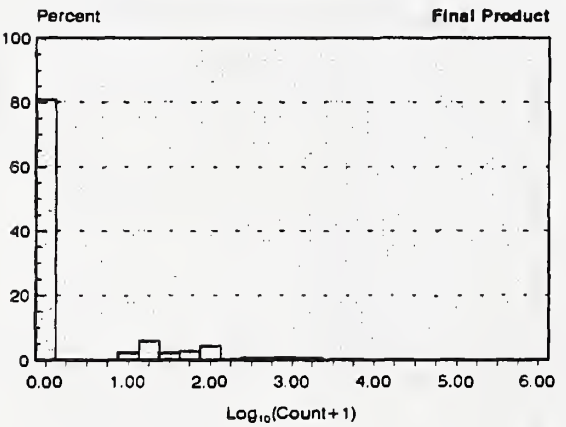


Figure 2. APC@20°C Distributions - Plant RF1

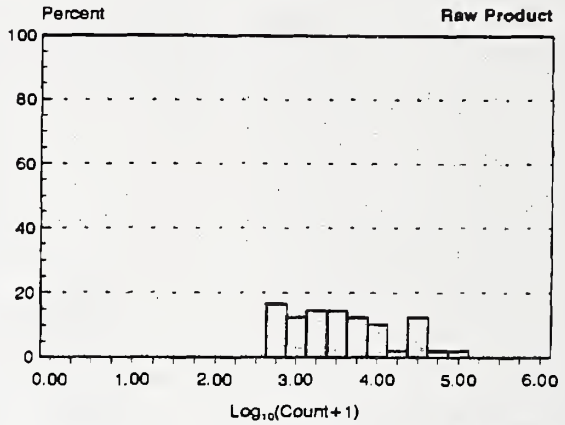
Phase 1

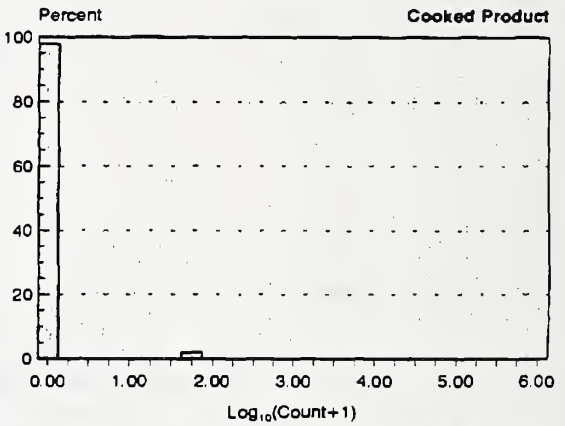


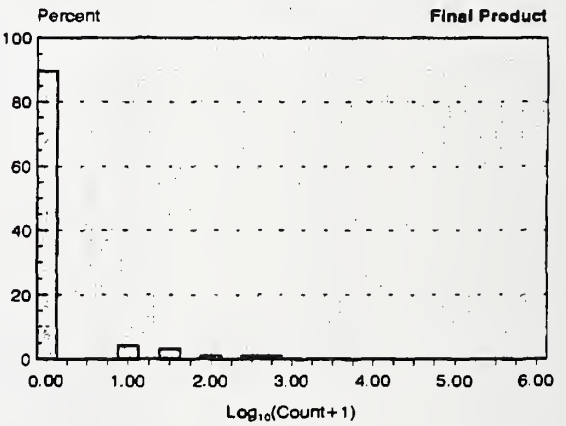




Phase 3







following packaging is indicative of the handling received. There were no practical differences between Phase I and III results.

Run charts for the six quantitative microbiology factors are presented in Figure 3. Centerlines (CL) could not be computed for any of the factors because there were insufficient positive results.

All 93 *Listeria* species swabs were negative in Phase I, and all 48 were negative in Phase III. This indicates effective sanitation procedures were used during both phases.

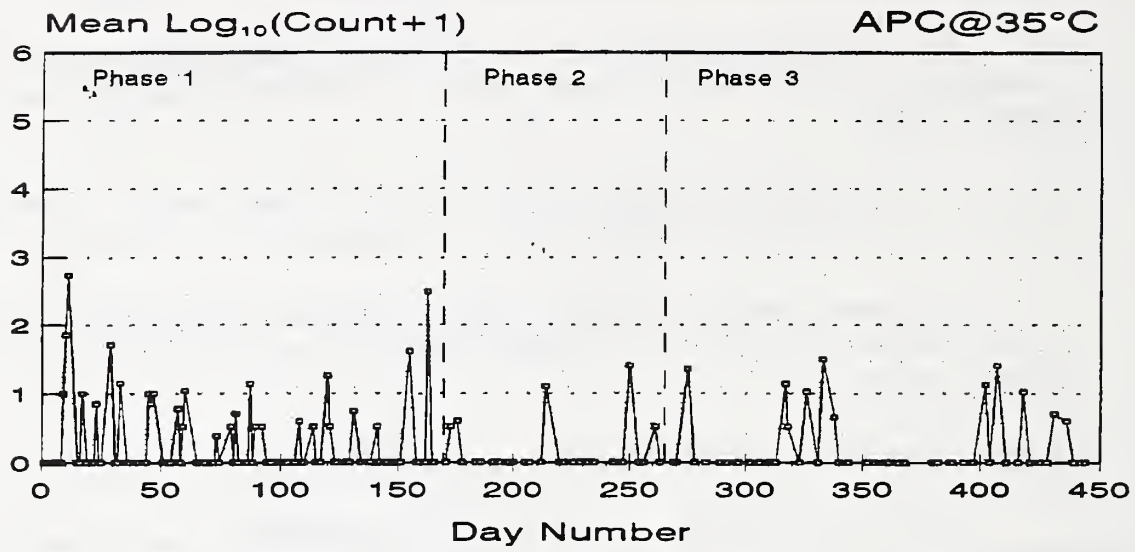
As discussed in the Methodology Chapter, chemistry testing was not performed on any of the Refrigerated Foods plants because the products were not amenable to the chemistry factors selected.

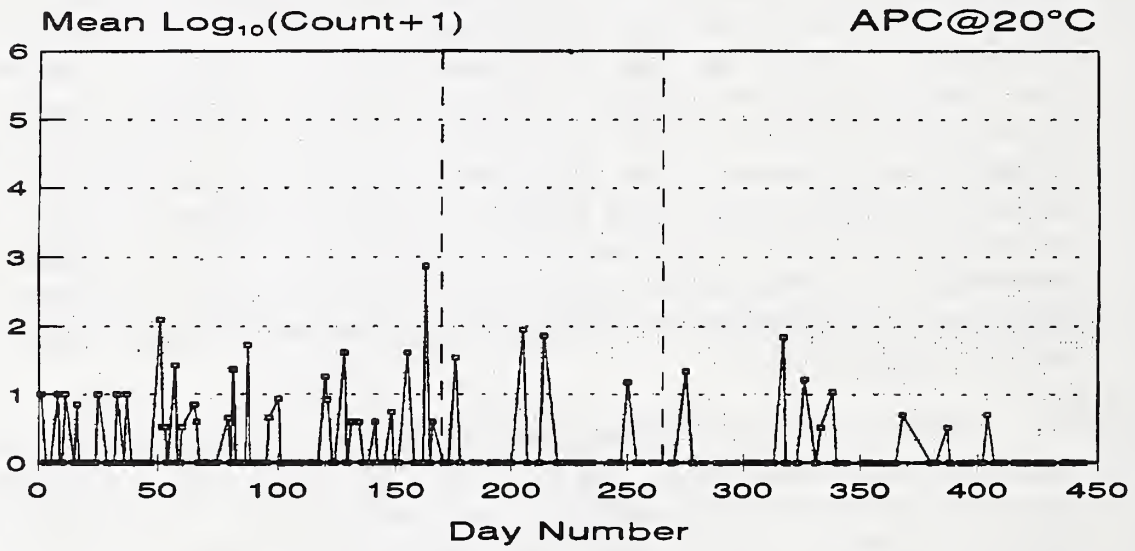
Refrigerated Foods plant 2 (RF 2):

Table 26 shows geometric means for the six quantitative microbiology factors at the different sampling points for RF 2. The table relates the sampling points to the generic HACCP Refrigerated Foods model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels of incoming raw material are low. The cooking process further reduced the levels of microorganisms -- in many cases, to below the level of detection. The levels of microorganisms in the final product are slightly higher, reflecting post-cooking handling of the product; however, the overall microbiological profile of the final product in both Phase I and Phase III is indicative of good processing procedures. In general, there was a lower proportion of samples containing detectable microorganisms in Phase III than in Phase I; however, there was little practical difference between the microbial levels in final product sampled during Phase I and final product sampled during Phase III.

Table 27 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III. Only APC @ 35°C and APC @ 20°C showed appreciable percents positive in the final product (see Pct values). The APC @35°C and APC @20°C distributions reflect the effectiveness of the cooking process. More samples tested negative in Phase III than in Phase I (See Figures 4 and 5).

Figure 3. Run Charts for Microbiology Data
Refrigerated Foods Plant 1 - Final Product





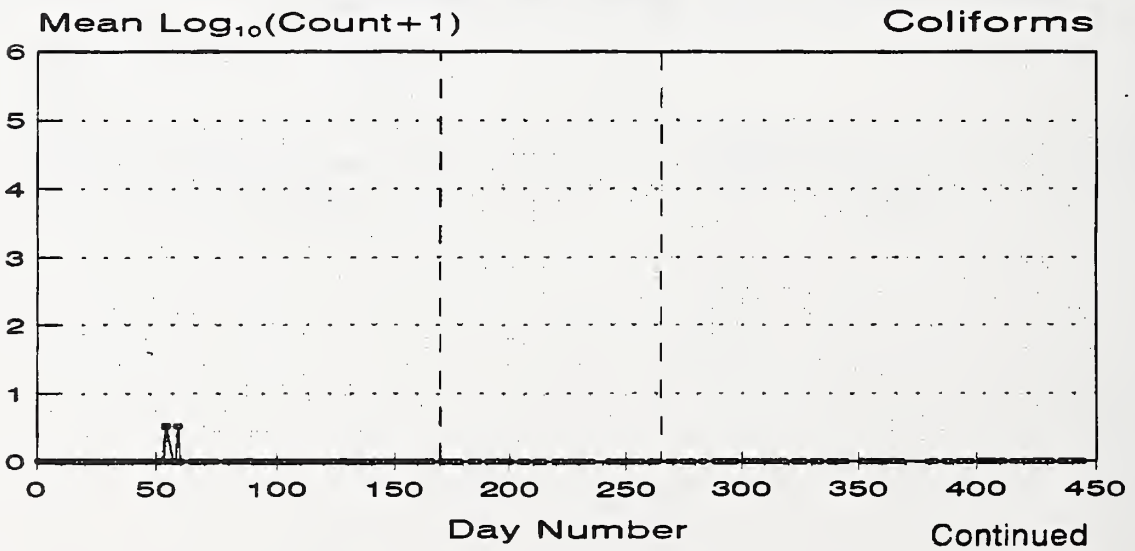


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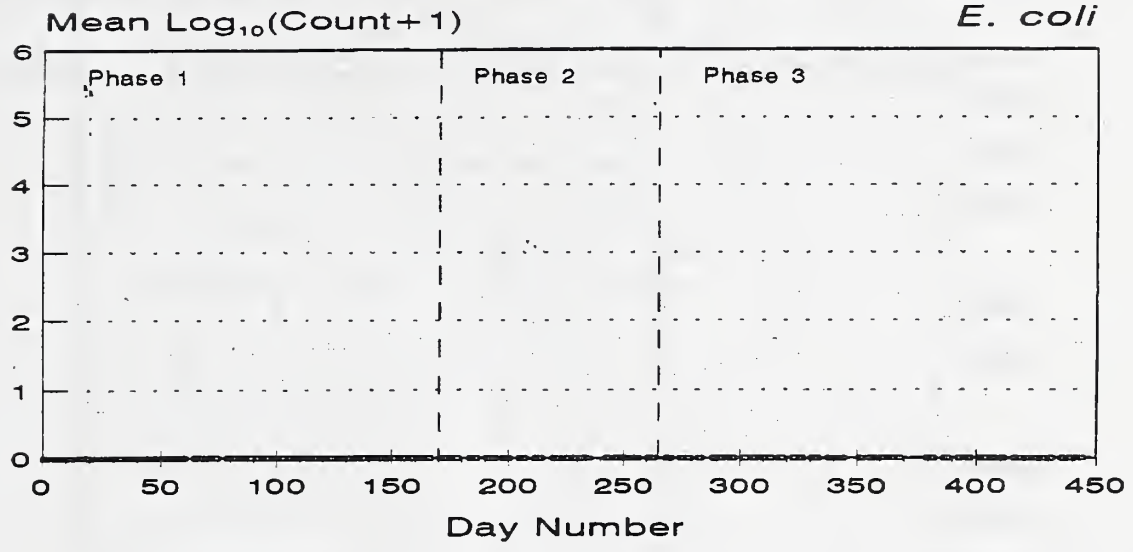
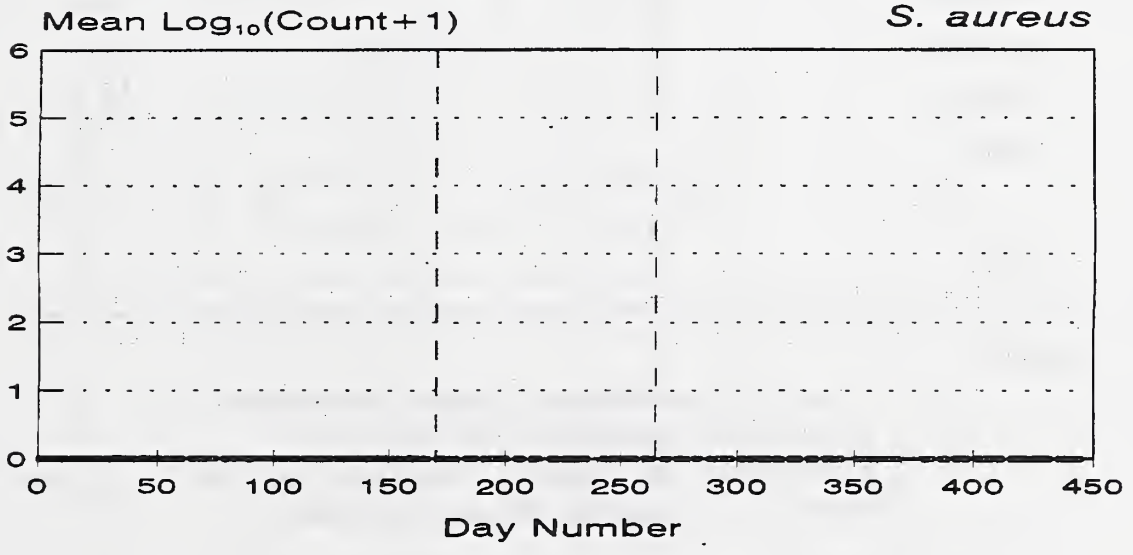
Figure 3 (continued). Run Charts for Microbiology Data
Refrigerated Foods Plant 1 - Final Product





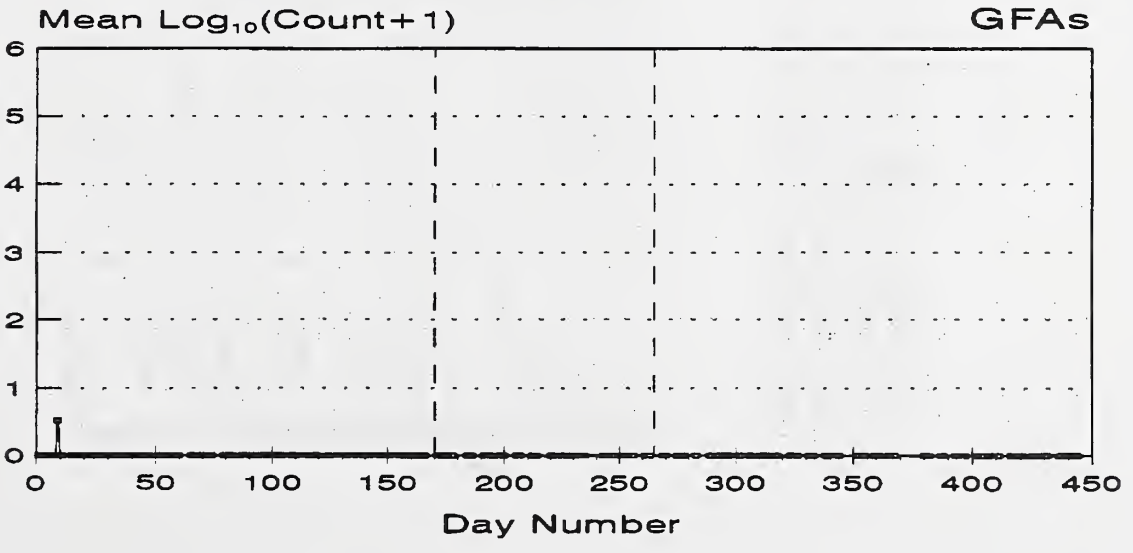


TABLE 26: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III REFRIGERATED FOODS PLANT 2

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
	671	1,180	2	1	1	1
	301	218	2	1	1	1
Cooking*						
Chilling*						
	7	4	1	1	1	1
	3	2	1	1	1	1
Assembly*						
Flush (Gas)*						
Seal Package						
Inspect Package*						
Labeling, etc.*						
Chilling*						
	7	9	1	1	1	1
	2	2	1	1	1	1
Storage*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

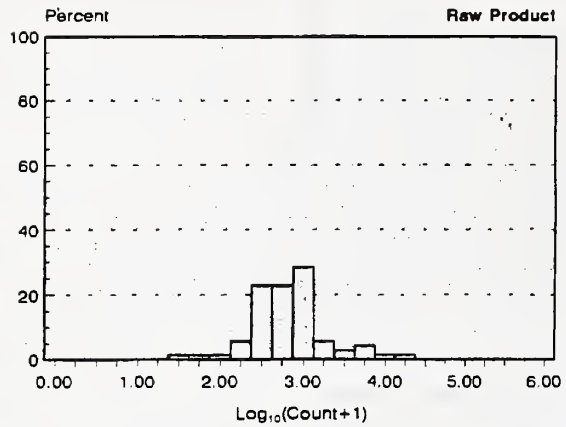
TABLE 27: SUMMARY STATISTICS FOR MICROBIAL FACTORS REFRIGERATED FOODS PLANT 2

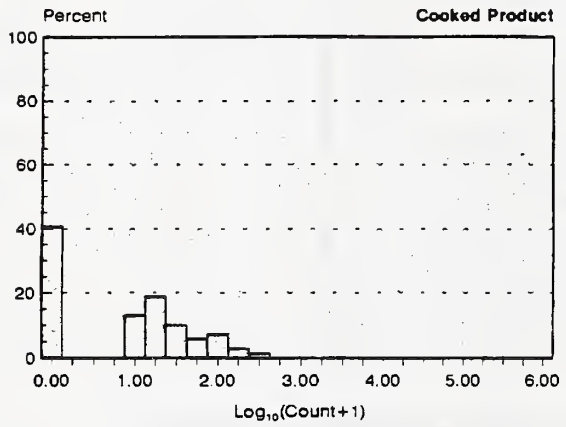
Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	70	100.0	2.8	.46	69	59.4	1.4	.40	70	58.6	1.5	.38
	3	41	92.7	2.7	.63	41	36.6	1.5	.58	41	26.8	1.4	.70
APC @20°C	1	70	100.0	3.1	.59	69	40.6	1.4	.45	70	58.6	1.6	.45
	3	41	87.8	2.7	.69	41	22.0	1.7	.66	41	17.1	1.6	.75
Coliforms	1	70	14.3	1.3	.24	69	0.0			70	1.4	1.3	
	3	41	9.8	1.9	1.41	41	0.0			41	0.0		
E. coli	1	70	0.0			69	0.0			70	0.0		
	3	41	0.0			41	0.0			41	0.0		
S. aureus	1	70	0.0			69	0.0			70	0.0		
	3	41	0.0			41	0.0			41	0.0		
GFAs	1	70	1.4	1.0		69	1.4	1.0		70	1.4	0.0	
	3	41	7.3	1.3	.58	41	1.7	1.0		41	4.9	0.0	0.0

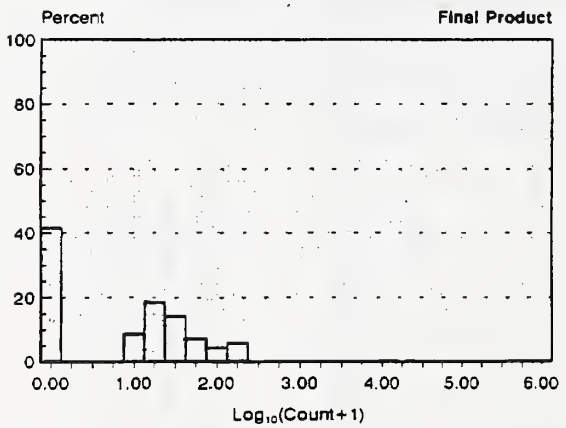
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

Figure 4. APC@35°C Distributions - Plant RF2

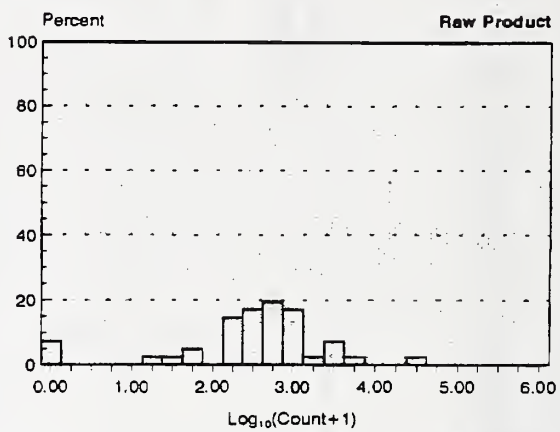
Phase 1

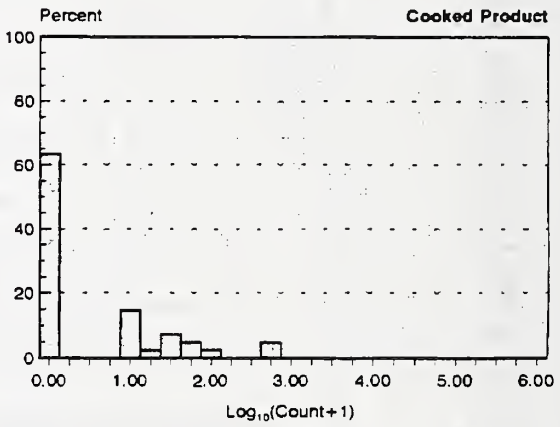






Phase 3





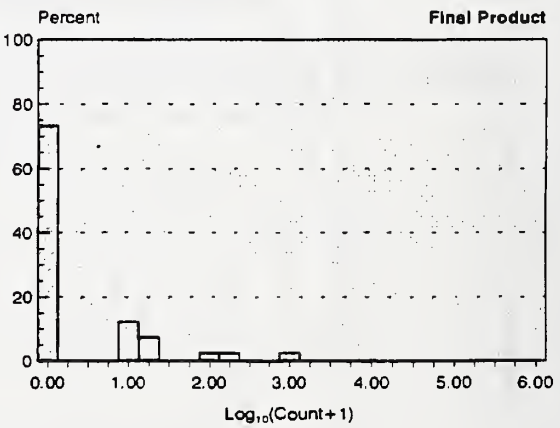
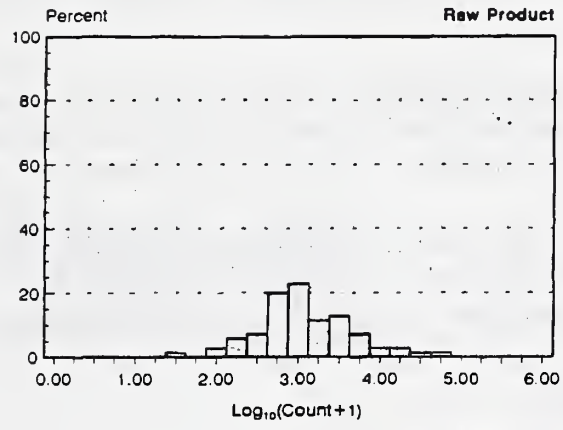
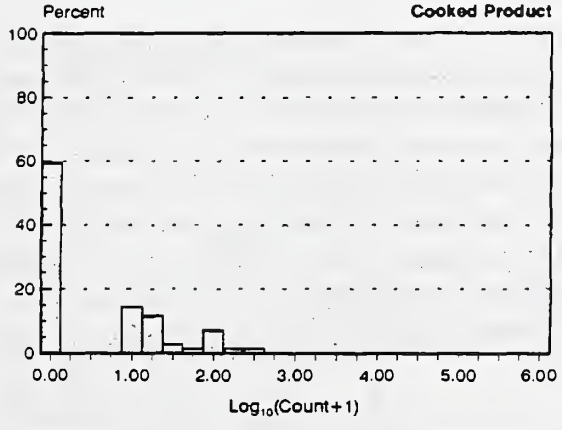
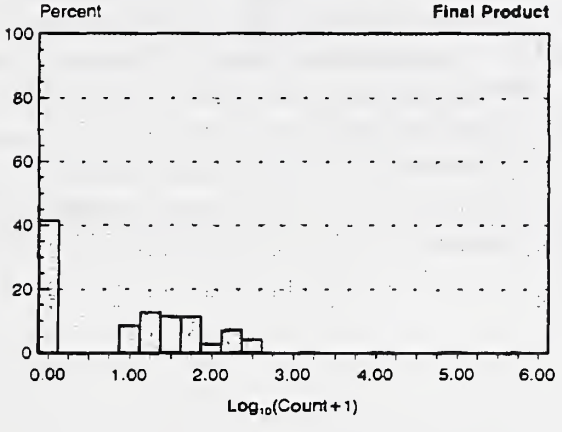


Figure 5. APC@20°C Distributions - Plant RF2

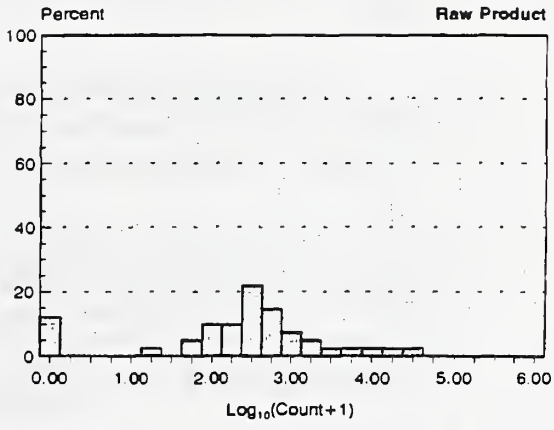
Phase 1

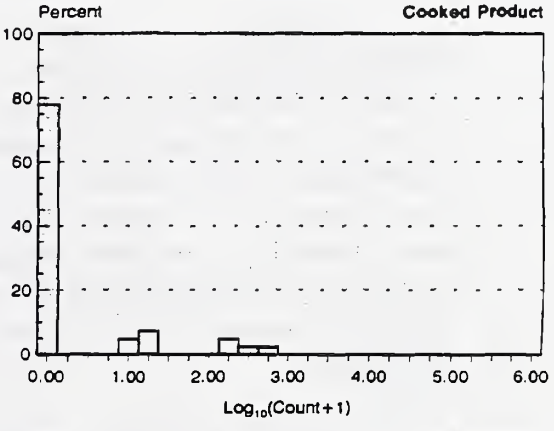


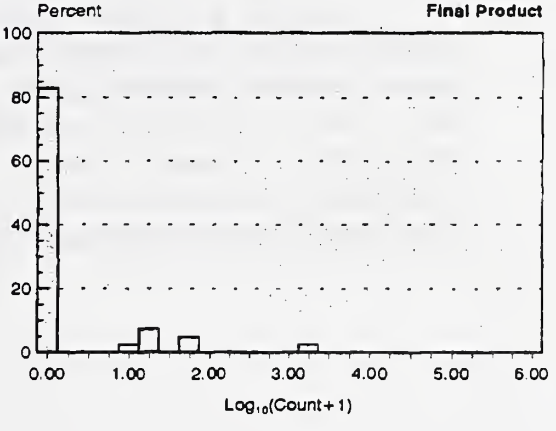




Phase 3







Run charts for the six quantitative microbiology factors are presented in Figure 6. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C and APC @ 20°C. There are runs of points below the centerline in Phase III for both APC @ 35 (starting on days 252 and 294) and APC @ 20 (starting on days 252 and 305). This indicates that a shift to a lower mean count/gm occurred in Phase III for these factors.

All 69 *Listeria* species swabs were negative in Phase I. One of 41 swabs was positive in Phase III. The occasional presence of *Listeria* species in environmental samples is not uncommon, but indicates the need to monitor cleaning and disinfection procedures closely.

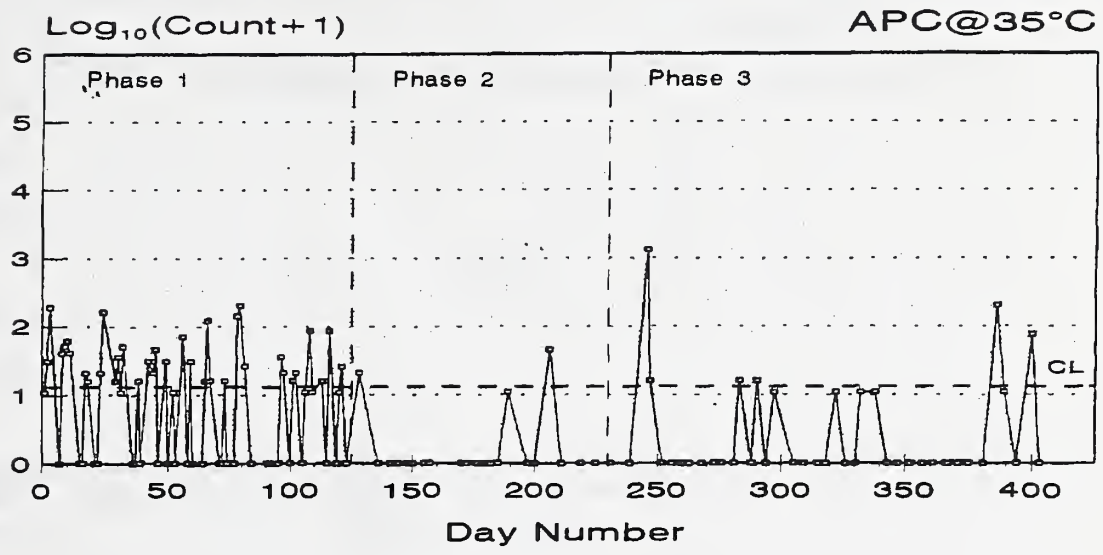
In summary, RF 2 showed a decrease in mean count/gm for both APC @35°C and APC @ 20°C. The microbiological profile of product produced during both phases was indicative of good manufacturing procedures including effective process control.

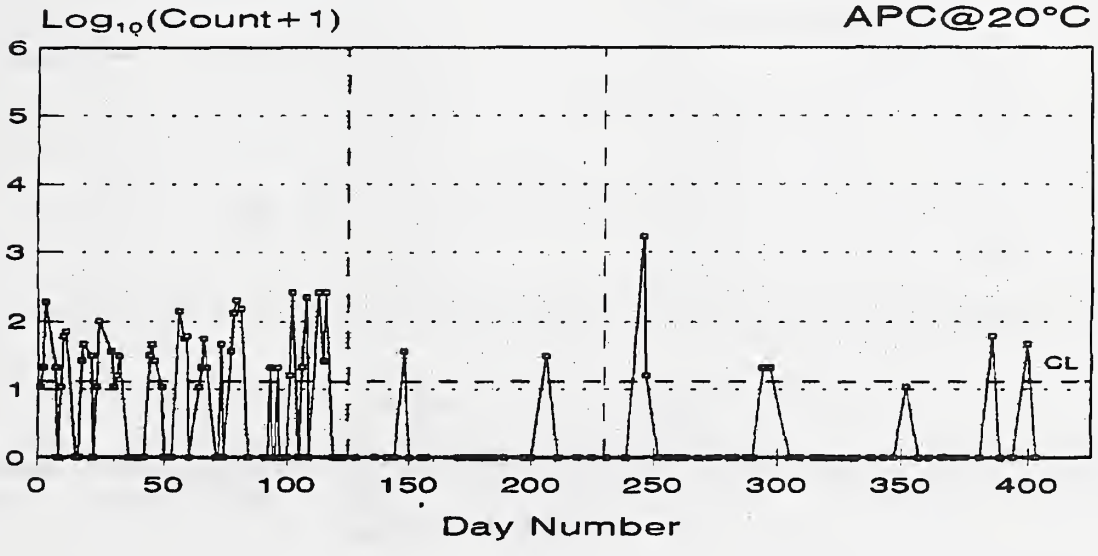
Refrigerated Foods plant 3 (RF 3):

Table 28 shows geometric means for the six quantitative microbiology factors at the different sampling points at RF 3, during Phases I and III. The table relates the sampling points to the generic HACCP Refrigerated Foods model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels of incoming raw material were low. The cooking process reduced the levels of microorganisms even further -- in many cases, to the level of detection or below. The levels of microorganisms in the final product are slightly higher, reflecting post-cooking handling of the product or combination with uncooked ingredients; however, the overall microbiological profile of the final product in both Phase I and Phase III is indicative of good processing procedures.

Table 29 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III. There were a greater number of samples for final product because duplicate final product samples were collected each sampling day in this plant. Only APC @ 35°C and APC @ 20°C showed appreciable percents positive in final product (see Pct values). Figures 7 and 8 display RF 3's APC @ 35° and 20° C results. The results show the effectiveness of the cooking process in reducing overall microbial levels. The effect of post-cooking handling is shown.

Figure 6. Run Charts for Microbiology Data
Refrigerated Foods Plant 2 - Final Product





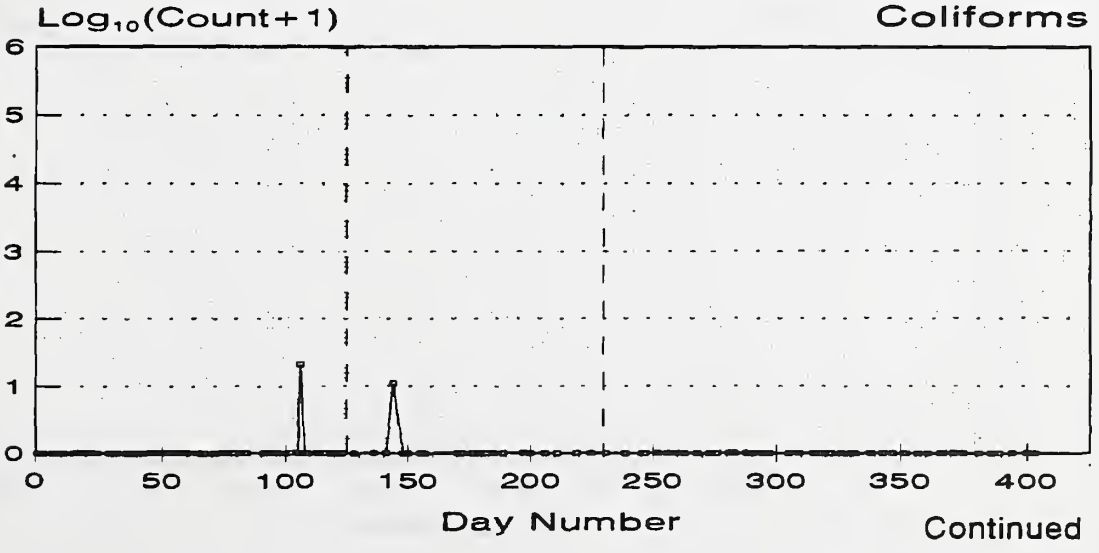


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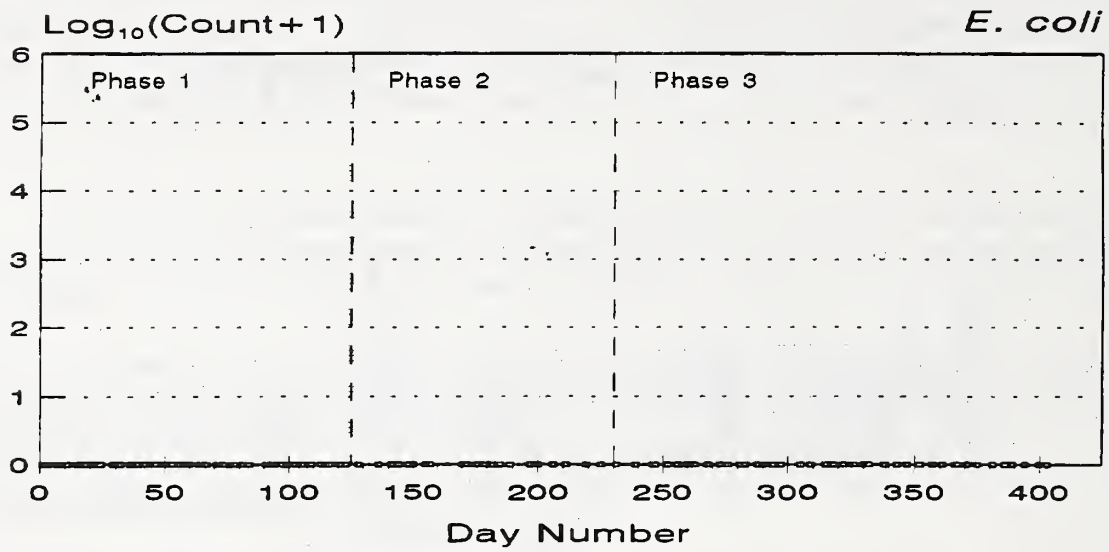
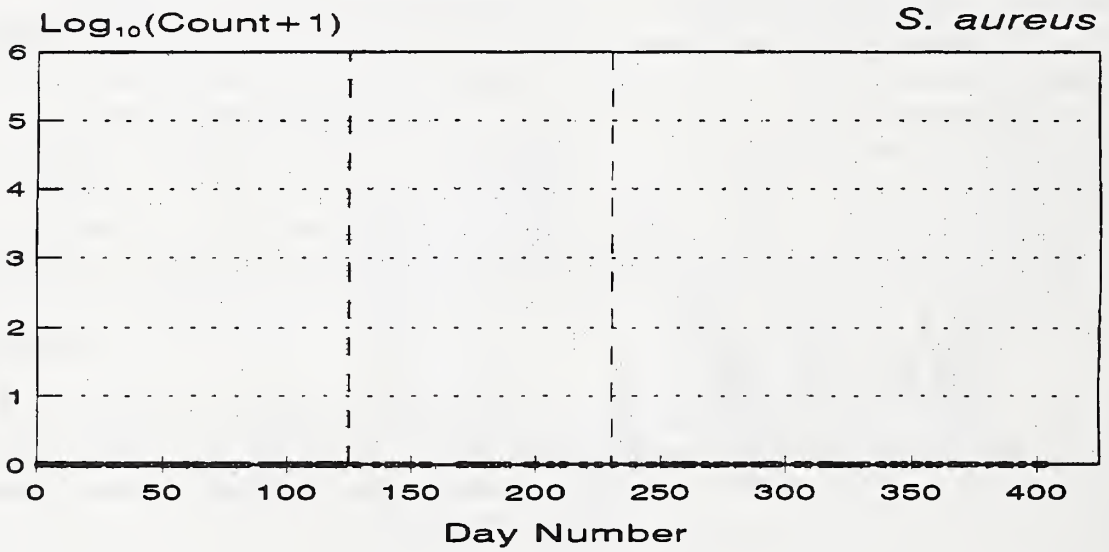
Figure 6 (continued). Run Charts for Microbiology Data.
Refrigerated Foods Plant 2 - Final Product





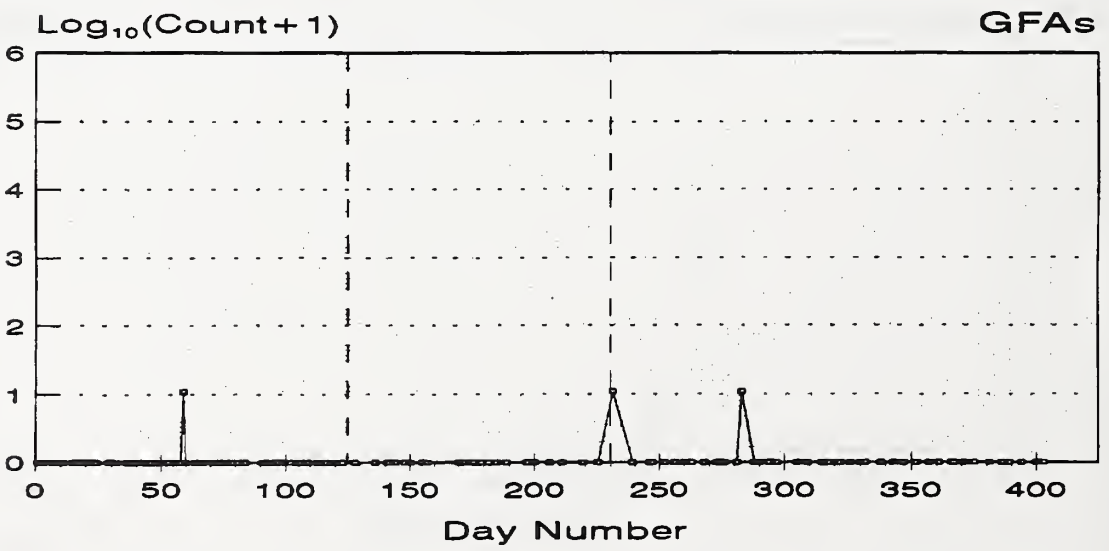


TABLE 28: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III REFRIGERATED FOODS PLANT 3

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
	38,100	215,000	239	20	2	8
	85,500	842,000	145	59	1	8
Cooking*						
Chilling*						
	6	5	1	1	1	1
	4	3	1	1	1	1
Assembly*						
Flush (Gas)*						
Seal Package						
Inspect Package*						
Labeling, etc.*						
Chilling*						
	31	19	1	1	1	1
	83	51	1	1	1	1
Storage*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

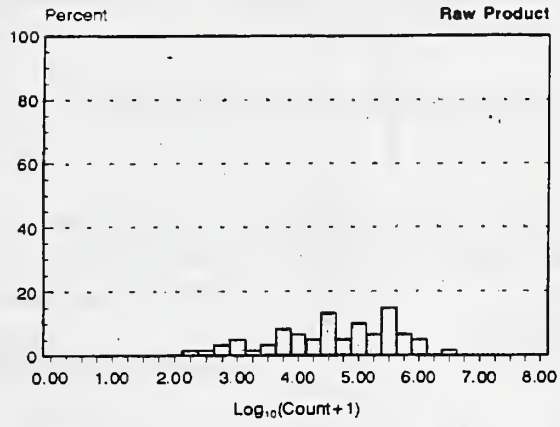
TABLE 29: SUMMARY STATISTICS FOR MICROBIAL FACTORS REFRIGERATED FOODS PLANT 3

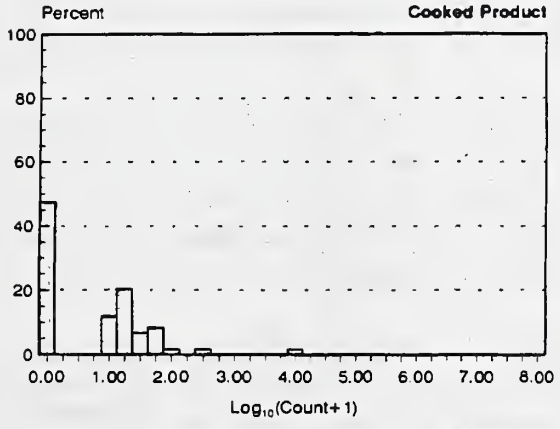
Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	60	100.0	4.6	1.00	59	52.5	1.4	.59	120	85.8	1.7	.57
	3	26	100.0	4.9	1.01	27	44.4	1.4	.52	54	92.6	2.1	.87
APC @20°C	1	60	100.0	5.3	.97	59	44.1	1.6	.67	120	75.0	1.7	.68
	3	26	100.0	5.9	.91	27	22.2	1.8	.99	54	85.2	2.6	.95
Coliforms	1	60	93.3	2.5	.74	59	5.1	1.8	1.32	120	0.0		
	3	26	96.2	1.8	.68	27	0.0			54	0.0		
E. coli	1	60	65.0	0.0	.58	59	0.0			120	0.0		
	3	26	96.2	0.0	.68	27	0.0			54	0.0		
S. aureus	1	60	8.3	2.4	.44	59	0.0			120	5.0	1.7	.73
	3	26	3.8	2.0		27	3.7	1.0		54	3.7	1.2	.27
GFAs	1	60	58.3	1.6	.44	59	0.0			120	7.5	1.7	.33
	3	26	69.2	1.3	.49	27	3.7	1.0		54	1.9	1.2	

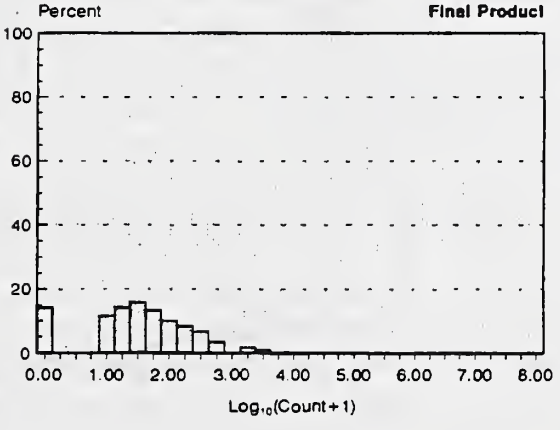
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

Figure 7. APC@35°C Distributions - Plant RF3

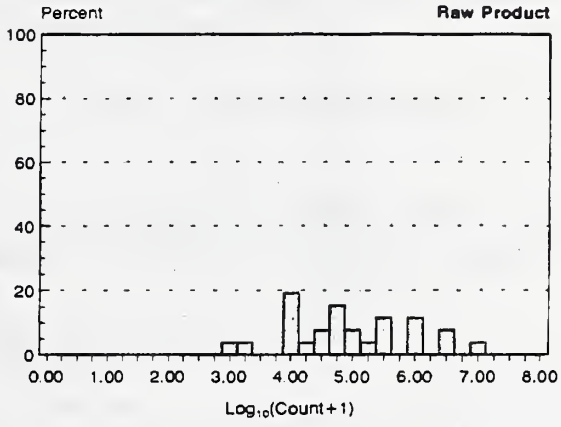
Phase 1

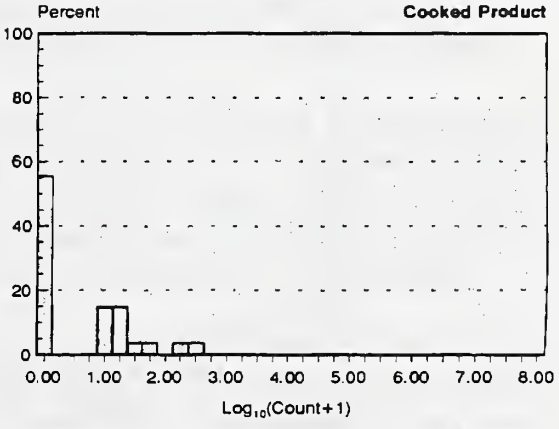






Phase 3





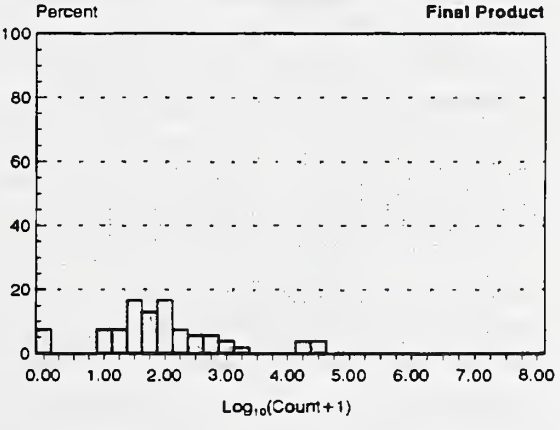
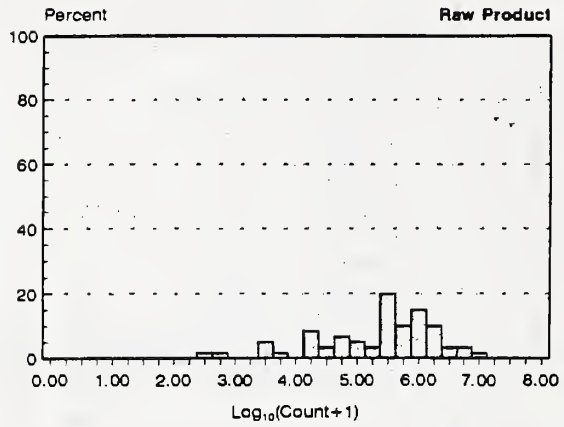
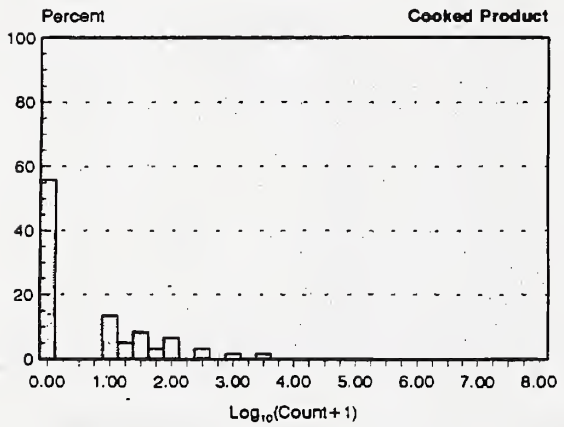
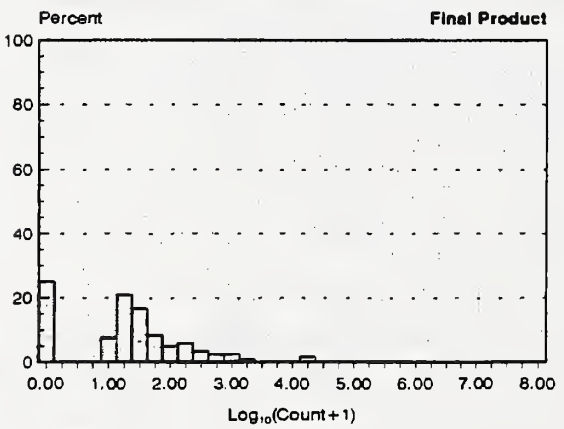


Figure 8. APC@20°C Distributions - Plant RF3

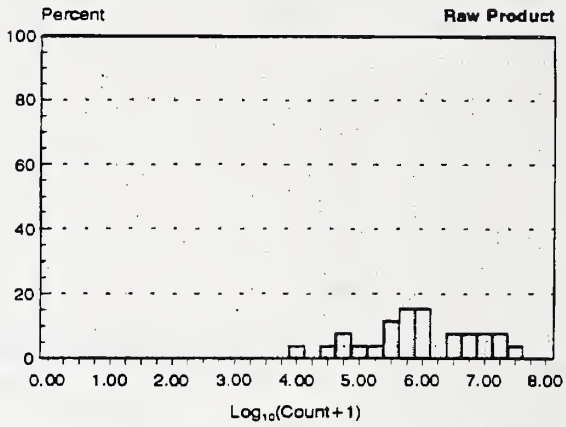
Phase 1

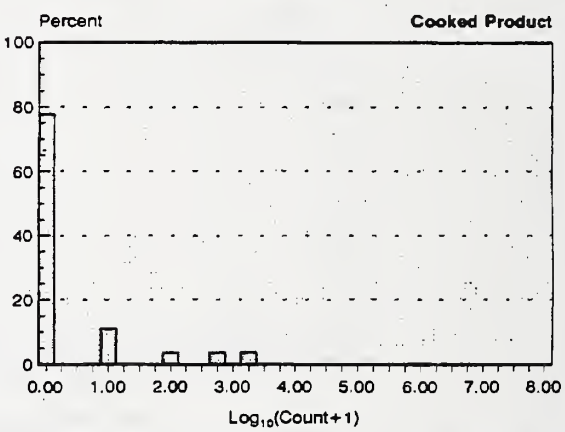


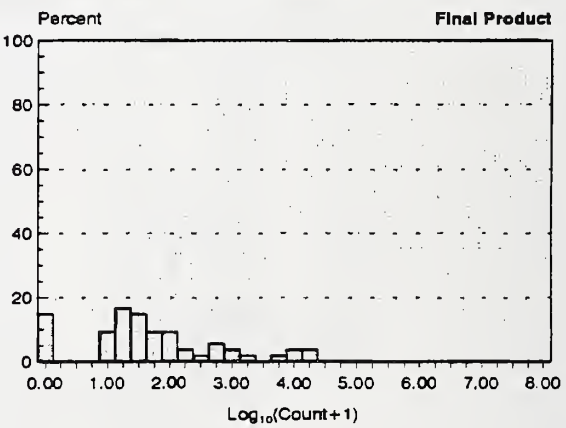




Phase 3







Run charts for the six quantitative microbiology factors are presented in Figure 9. There were sufficient positive results to compute a centerline (CL) for APC @ 35°C and APC @ 20°C. There is a run of points above the centerline in Phase III, starting at day 436, for APC @ 35°C. This indicates that a shift to a higher mean count/gm occurred in Phase III for this factor. The pattern for APC @ 20°C is similar, although these is no run of eight consecutive points above the CL. Levels for all other factors in Phase III were equal or less than those in Phase I.

All 57 *Listeria* species swabs were negative in Phase I, and all 23 were negative in Phase III.

In summary, RF 3 showed a shift to higher mean count/gm for APC @ 35°C. The microbiological profile of product produced during both phases is indicative of good manufacturing procedures.

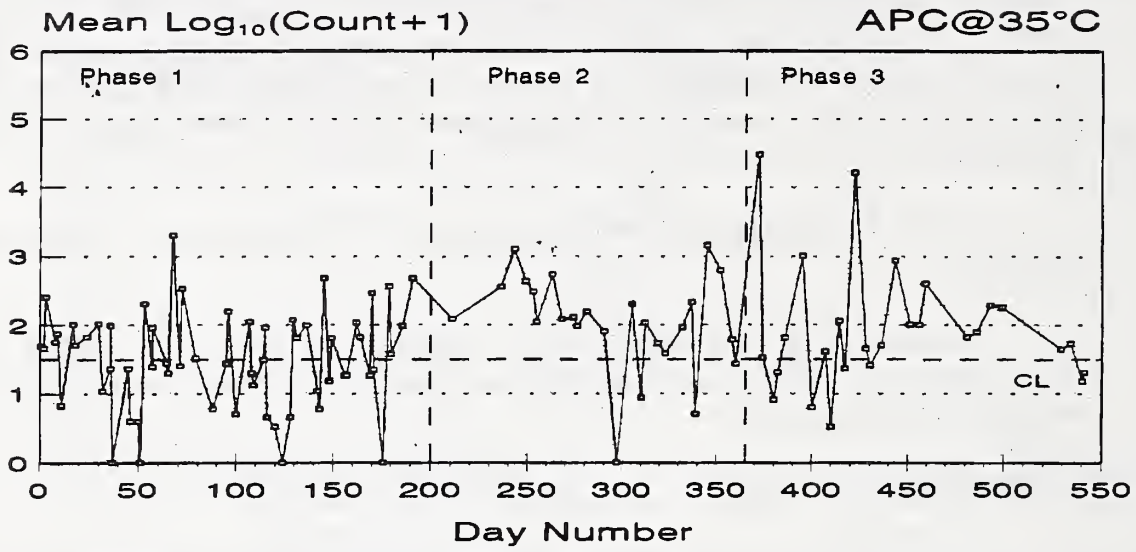
Cooked Sausage Plants:

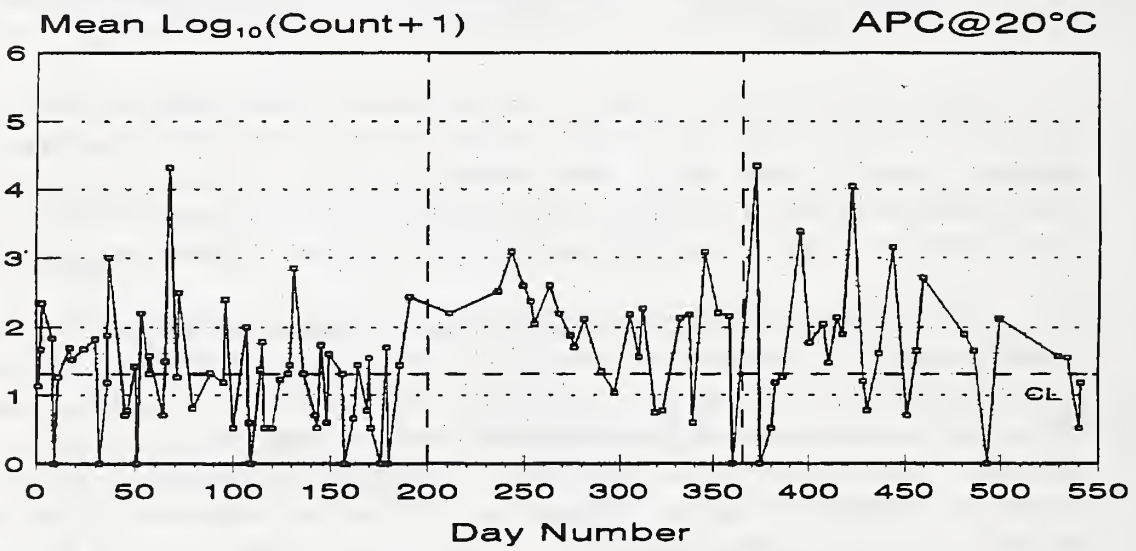
The quantitative data for the three Cooked Sausage plants included seven microbiology factors and two chemistry factors. The seven microbiology factors are listed in Chapter 2:

Samples for the first six factors were collected at three different control points in processing: (1) after stuffing; (2) after chilling and storage; and (3) from final packaged product. Results for these factors were reported in counts per gram. Swabs for *Listeria*-species tests were taken from four different finished product contact surfaces on an alternating basis. Results for *Listeria* were reported only as positive or negative (not quantified).

The sampling sites were purposely selected to bracket (i.e., before and after) critical control points in the production of cooked sausages. These critical points are those related to cooking, chilling, and post-cooking handling of the product. The cooking process is the only critical control point in the production process for this product where appreciable reduction of microbial levels can be expected. The sampling sites are depicted in Tables 30, 32 and 34 in relation to both the critical control points and other steps in the production process. The mean microbiological levels for each of the six factors at each of the sampling sites are shown in the same tables. The values in the tables for points prior to cooking show the microbiological condition of the raw material. The values immediately after cooking and chilling indicate the effectiveness of the cooking process in reducing microbial levels and the effectiveness of the chilling process in retarding multiplication of any survivors. The final values in the tables indicate the degree of sanitation practiced during the steps of the process leading to in the final packaged product. In these tables, as indicated, a value of one was assigned to samples which were negative to facilitate the calculation of the geometric mean. These tables show the relative levels for each microbiological factor at the various stages in

Figure 9. Run Charts for Microbiology Data
Refrigerated Foods Plant 3 - Final Product





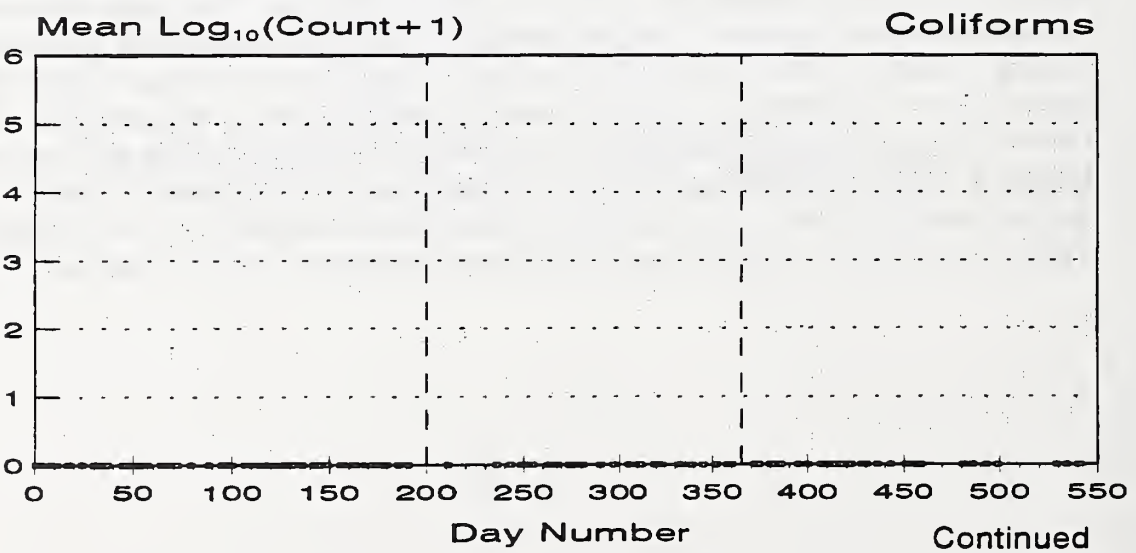


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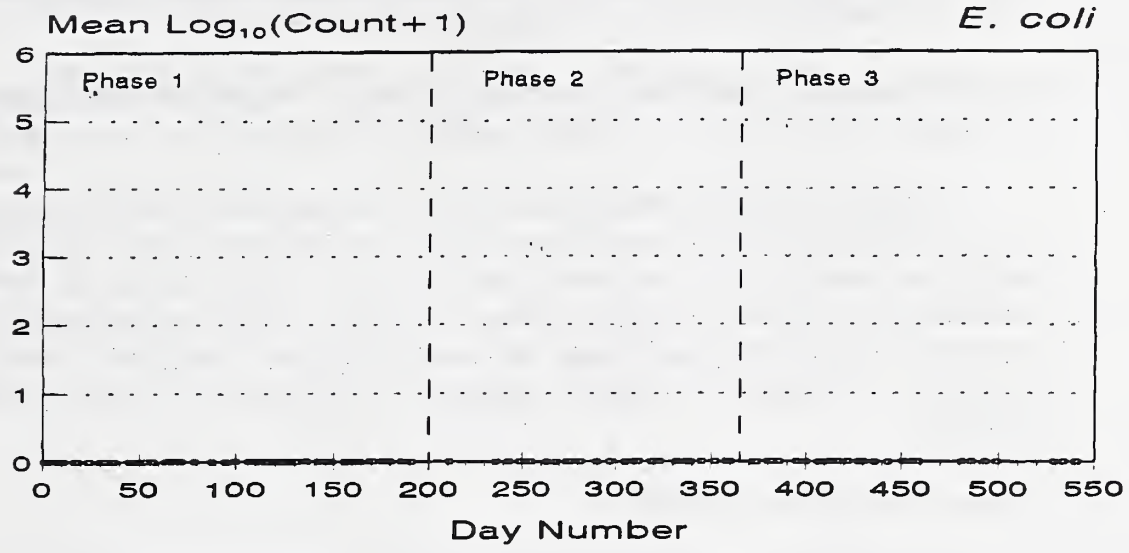
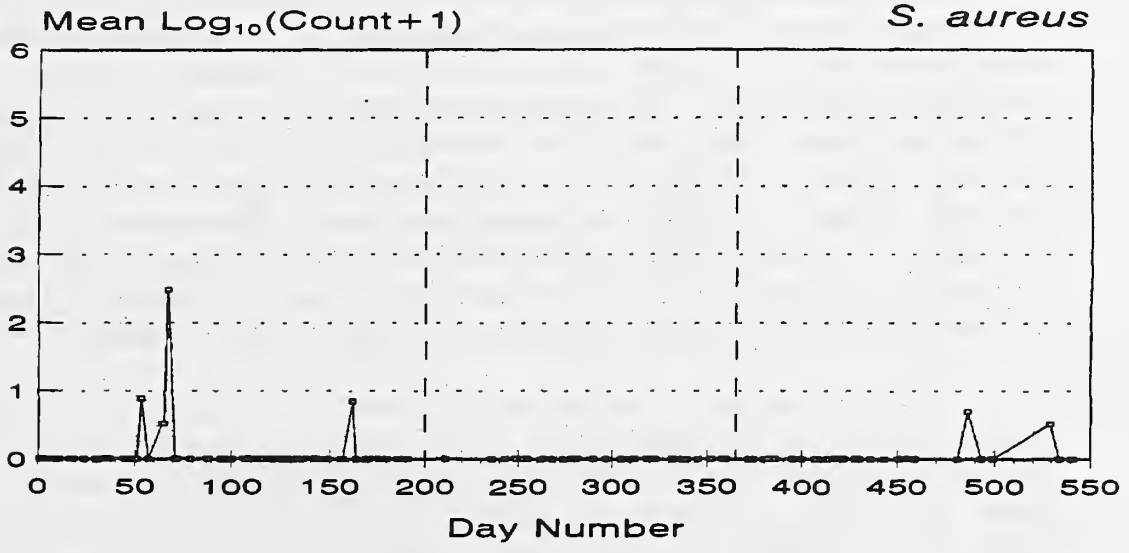
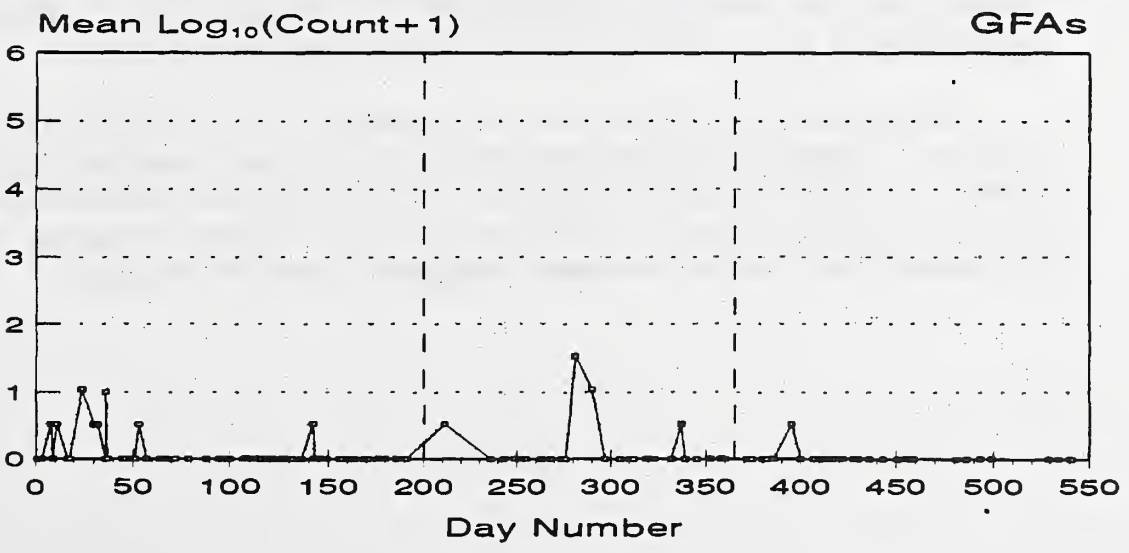
Figure 9 (continued). Run Charts for Microbiology Data.
Refrigerated Foods Plant 3 - Final Product







the production process and present what is known as the "microbiological profile" of the production process. Tables 31, 33, 35 present the percent of samples testing positive for each of the microbiological factors and the log average level for each.

The two chemistry factors were nitrites and salt (brine). Samples of final product were tested for nitrites and salt (brine). In addition, samples of curing mixtures were tested for nitrites.

The plan to collect sample sets on 30 to 50 different days during both the baseline and operational phases (Phases I and III) was fulfilled for all three Cooked Sausage plants. The results were analyzed to check each plant's ability to control its process and to compare characteristics of product produced in Phases I and III. Results are discussed separately for each plant. Results for microbiology and chemistry factors from Phase I were shared with the plants at the beginning of Phase II, and results from Phase II were shared as they became available.

Cooked Sausage plant 1 (CS 1)

Table 30 shows geometric means for the six quantitative microbiology factors at the different sampling points in CS 1 during Phases I and III. It also relates the sampling points to the generic HACCP Cooked Sausage model and demonstrates the change in microbial profile during the process. The microbiological levels of incoming raw material were low. The cooking process further reduced the level of microorganisms -- in many cases, to below the level of detection. The level of microorganisms in the final product was similar to that just after cooking and chilling, indicating good handling procedures during peeling and packaging. The overall microbiological profile of the final product in both Phases I and III was indicative of good processing procedures. There was little practical difference between the microbial profiles of product sampled during Phase I versus Phase III.

Table 31 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III. There are greater numbers of samples for final product because duplicate final product samples were collected each sampling day in this plant. Only APC @ 35°C and APC @ 20°C showed appreciable percent positive in final product (see Pct values). Figures 10 and 11 display the APC @ 35°C and APC @ 20°C distribution and demonstrate the effectiveness of the cooking process. Little effect of post-cooking handling was evident. Phase I and Phase III results are similar.

Run charts for the six quantitative microbiology factors in final product are presented in Figure 12. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C and APC @ 20°C. For APC @ 35°C there were runs of points below the centerline in Phase I (starting on day 73) and in Phase III (starting on day 343). This indicates that shifts to lower mean count/gram occurred for this factor.

TABLE 30: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III COOKED SAUSAGE PLANT 1

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
Formulation*						
Chop/Blend/Emulsify*						
Stuffing						
	4,180	11,600	3	2	3	4
	4,140	13,800	3	1	2	2
Cook/Smoke*						
Showering						
Chill/Storage*						
	6	4	1	1	1	1
	7	8	1	1	1	1
Peeling*						
Packaging*						
	7	8	1	1	1	1
	6	8	1	1	1	1
Storage*						
Shipping/Distribution						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

TABLE 31: SUMMARY STATISTICS FOR MICROBIAL FACTORS COOKED SAUSAGE PLANT 1

Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	54	100.0	3.6	.69	56	57.1	1.3	.26	90	66.7	1.3	.25
	3	42	97.6	3.7	.79	42	59.5	1.4	.69	58	62.1	1.4	.55
APC @20°C	1	54	100.0	4.1	.74	56	41.1	1.4	.33	90	67.8	1.4	.40
	3	42	97.6	4.2	.80	42	59.5	1.5	.76	58	60.3	1.5	.53
Coliforms	1	54	35.2	1.5	.36	56	0.0			90	0.0		
	3	42	28.6	1.6	.62	42	0.0			58	3.4	1.0	.00
E. coli	1	54	18.5	1.2	.23	56	0.0			90	0.0		
	3	42	11.9	1.2	.37	42	0.0			58	0.0		
S. aureus	1	54	16.7	2.4	.58	56	0.0			90	0.0		
	3	42	14.3	2.0	.00	42	2.4	1.0		58	0.0		
GFAs	1	54	48.1	1.2	.37	56	0.0			90	0.0		
	3	42	21.4	1.3	.71	42	0.0			58	3.4	1.0	.00

Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

Figure 10. APC@35°C Distributions - Plant CS1

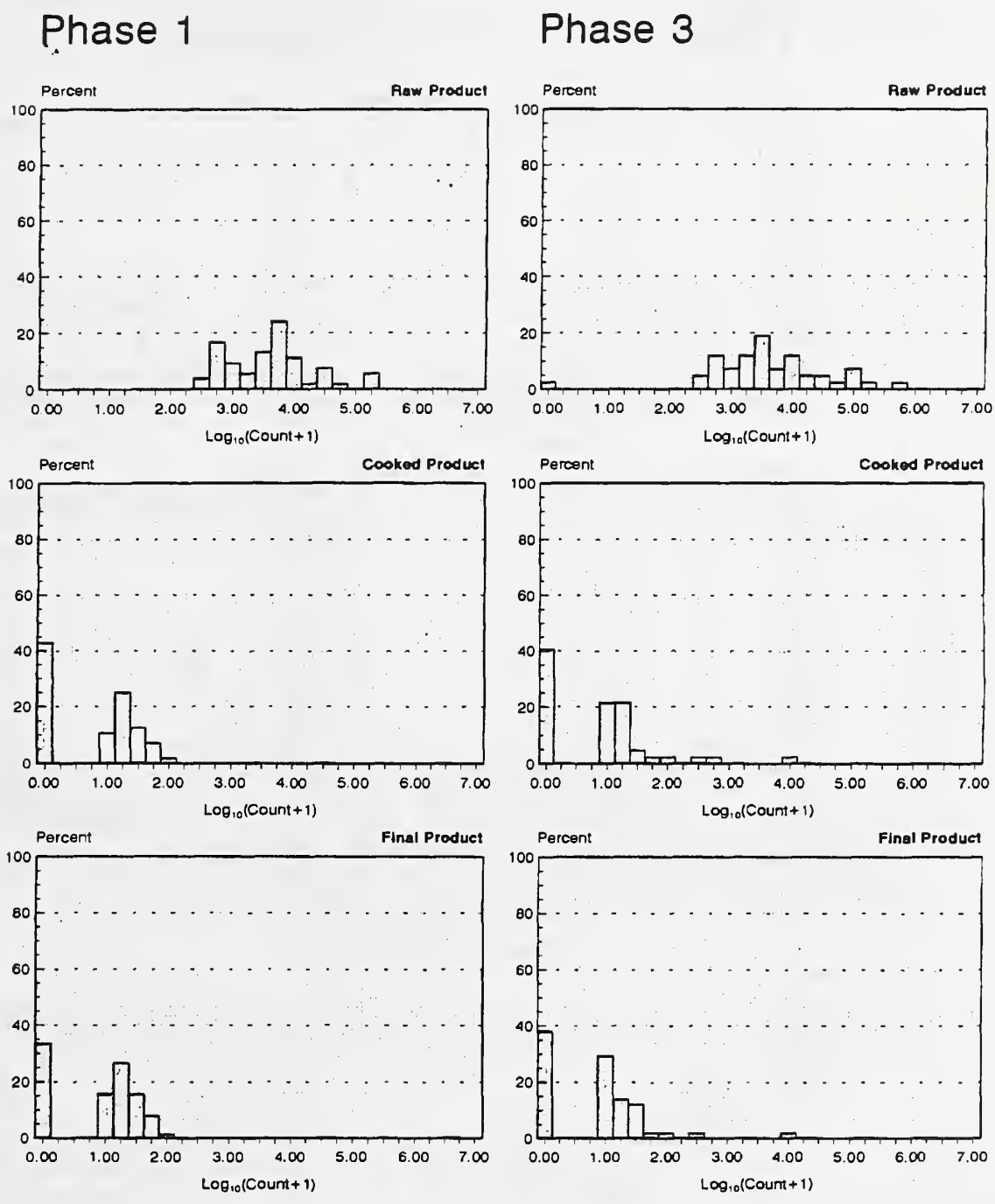
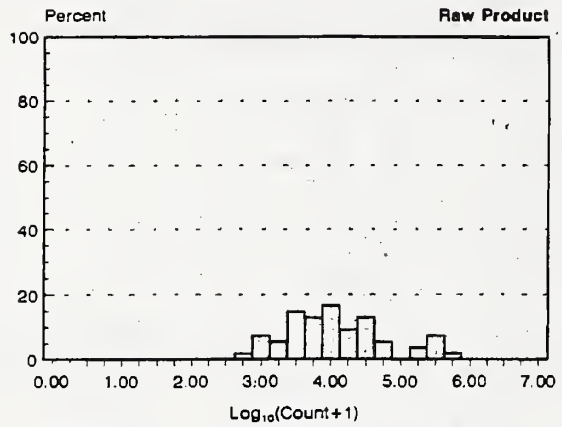
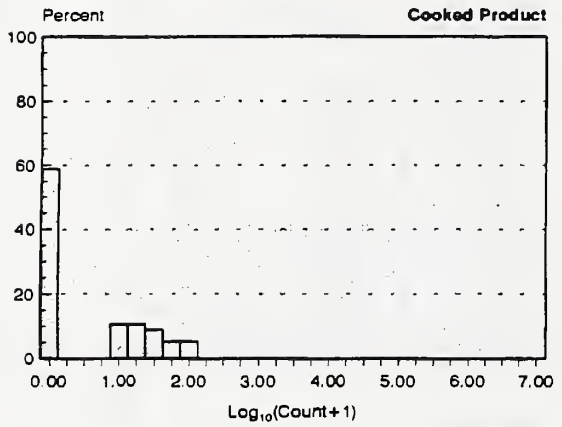
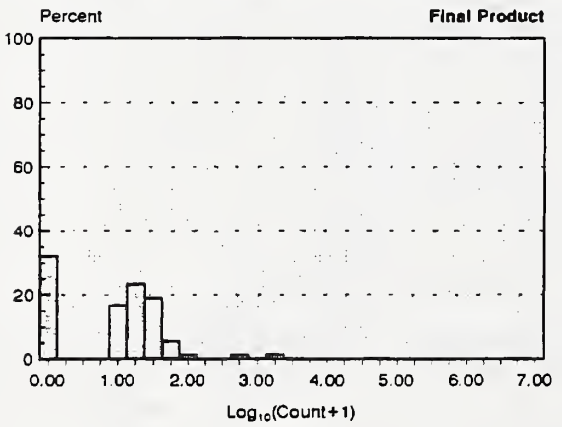


Figure 11. APC@20°C Distributions - Plant CS1

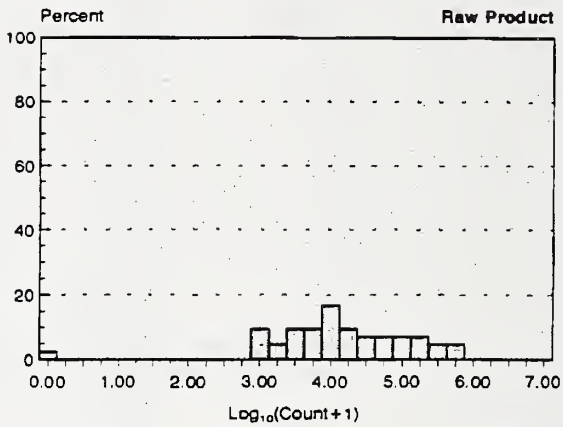
Phase 1

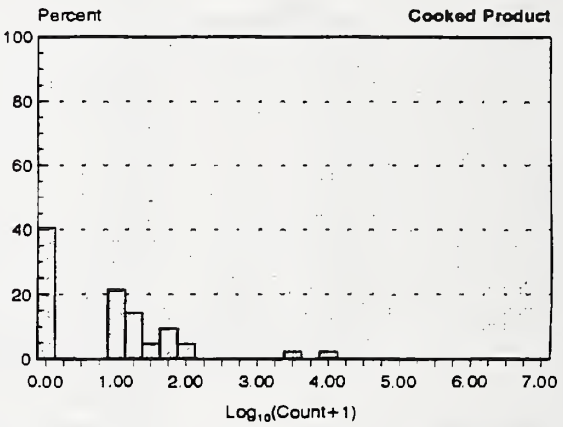






Phase 3





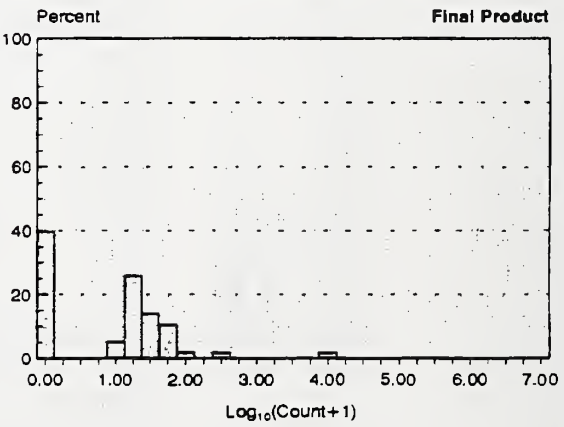
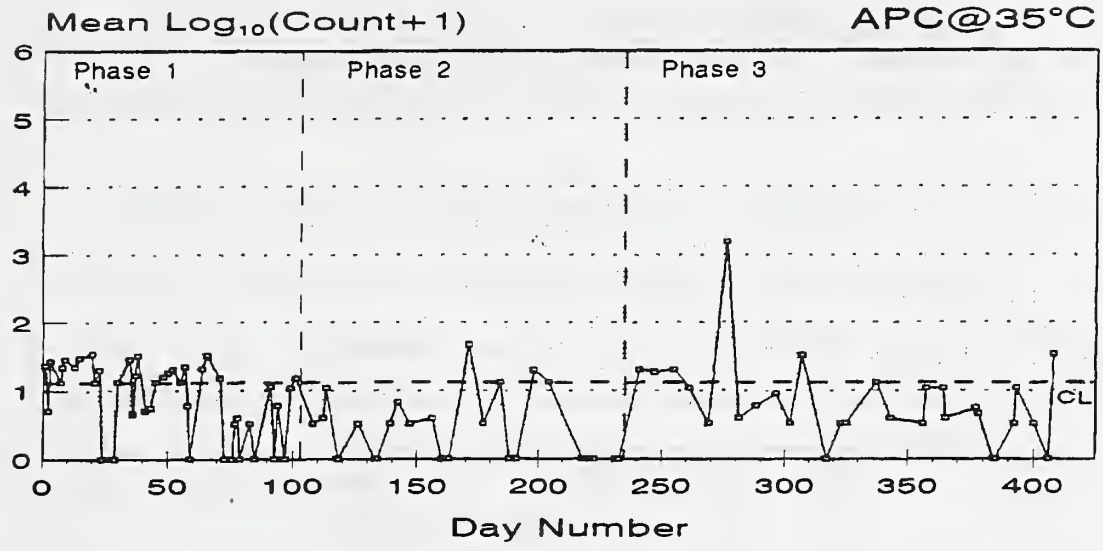
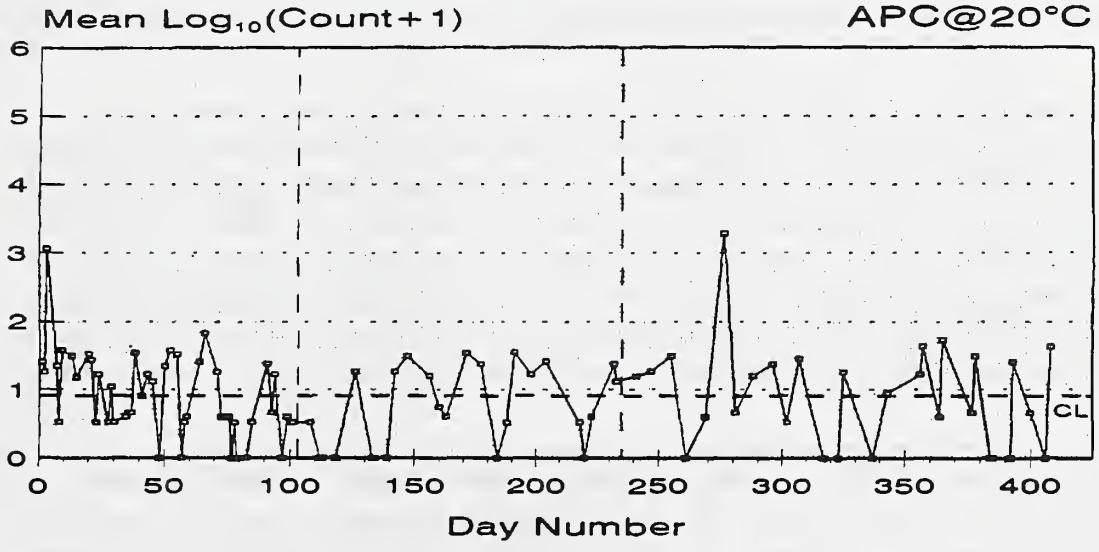


Figure 12. Run Charts for Microbiology Data
Cooked Sausage Plant 1 - Final Product





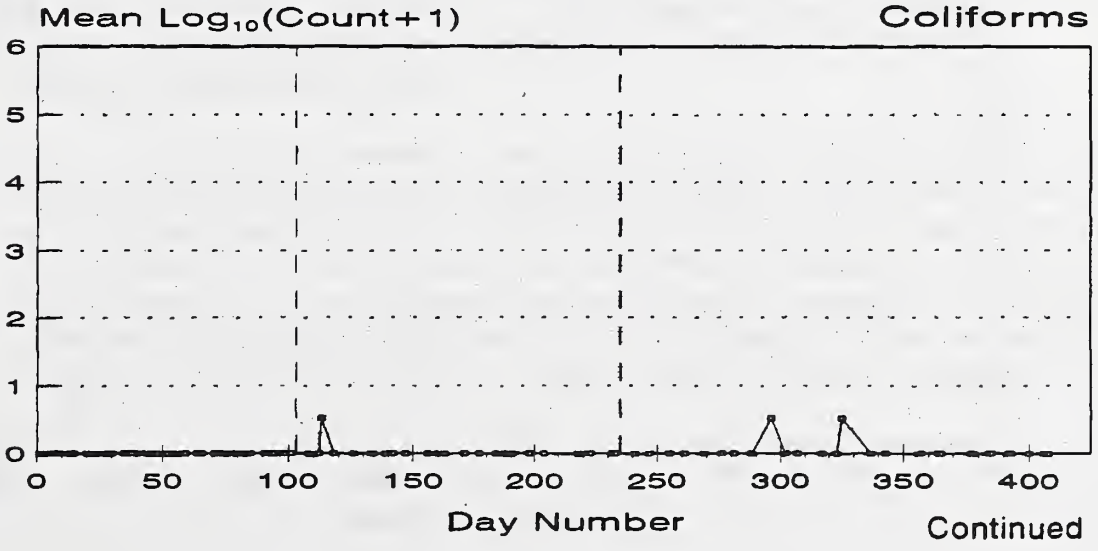


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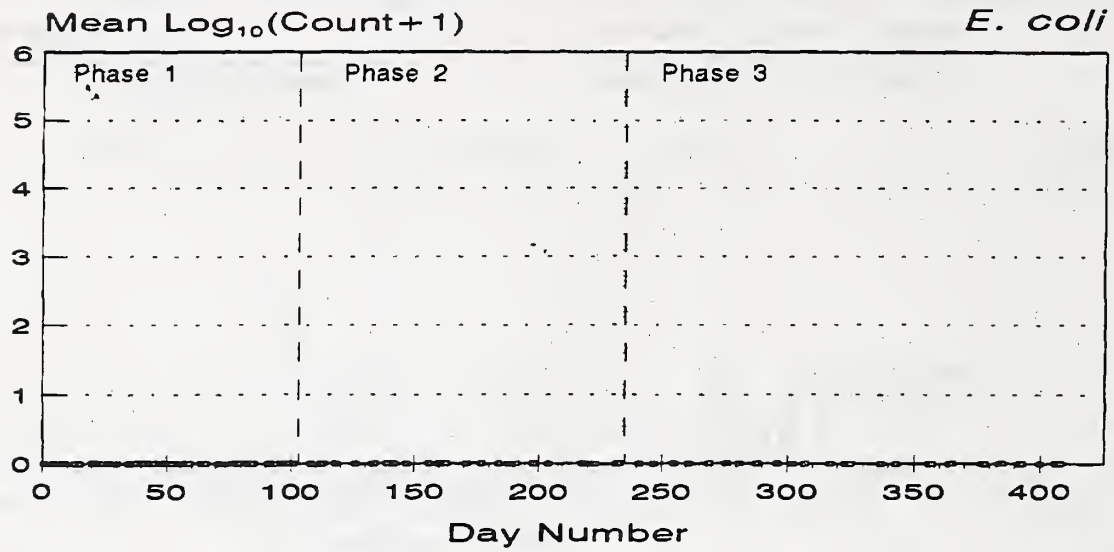
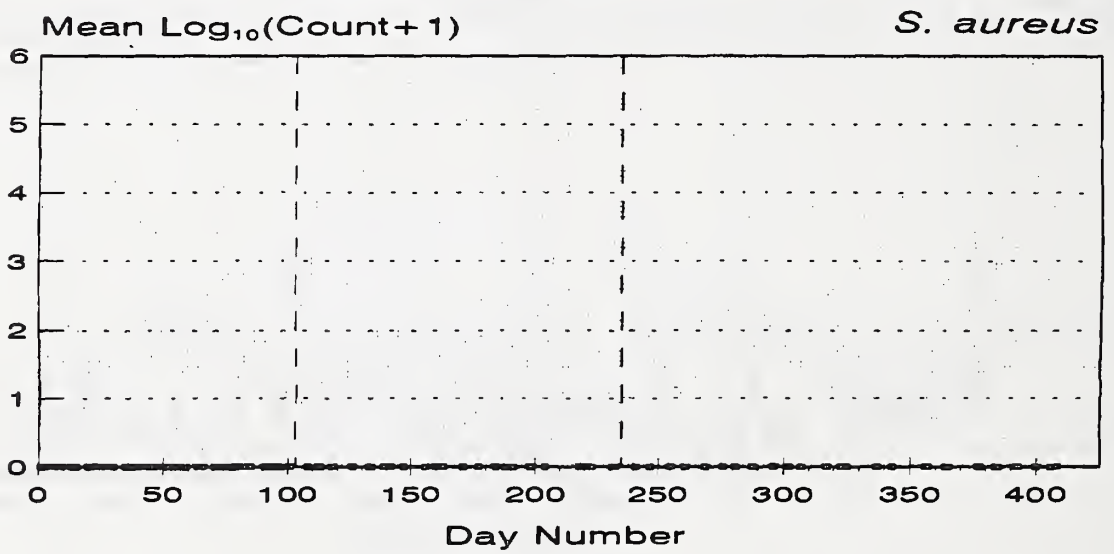
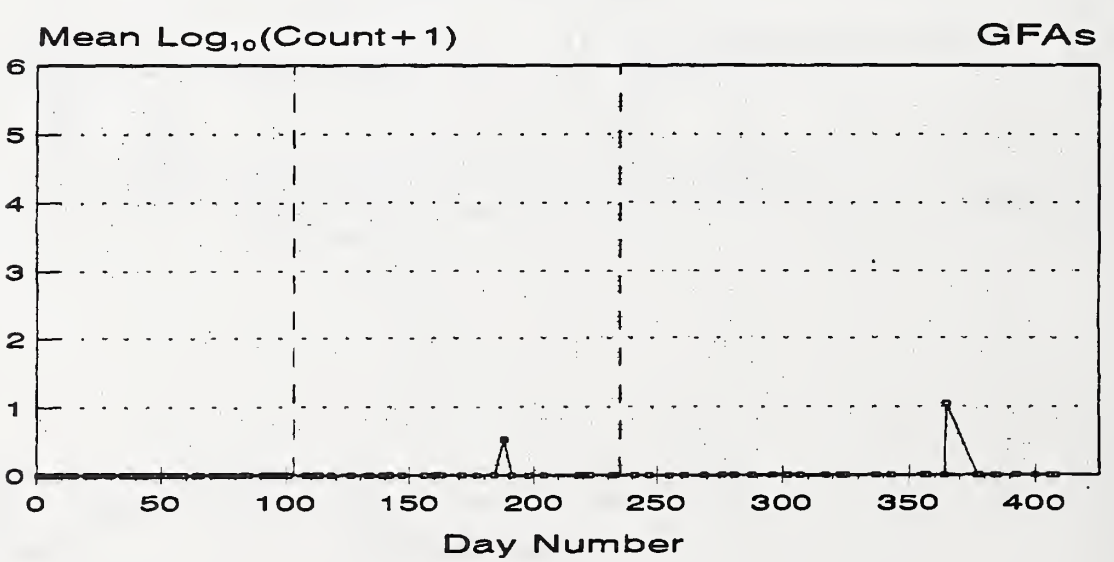
Figure 12 (continued). Run Charts for Microbiology Data
Cooked Sausage Plant 1 - Final Product







All 56 *Listeria* species swabs were negative in Phase I. and one of 42 was positive in Phase III. The occasional presence of *Listeria* species in environmental samples is not uncommon, but indicates the need to monitor cleaning and disinfection procedures closely.

Table 32 displays the chemistry testing results of finished product in Phase I and III.

TABLE 32: NITRITE AND BRINE CHEMISTRY TESTING RESULTS FOR CS 1

Analyte	Phase	N	Mean	Minimum	Maximum
Nitrite	1	58	33.4	11.0	52.0
	3	38	42.6	33.0	52.0
Brine	1	58	3.9	3.3	4.7
	3	38	3.9	3.5	4.6

The mean nitrite values (Table 32) for Phases I and III were significantly lower than maximum allowable amount of 156 parts per million (ppm) in the formulation of the product, also the maximum values observed for both phases (52 ppm) were significantly lower than the maximum allowable value of 156 ppm. It can be seen that there is a large variation in the extent of nitrite depletion between individual products. This is since sodium nitrite is relatively unstable and small variations in storage time, storage temperature, and matrix composition can have large effects upon the depletion rate of this analyte. The percentage of brine seen in the above table is within the normal range for cooked sausages in Phases I and III.

In summary, the HACCP microbiological assessment in Cooked Sausage Plant CS 1 showed a decrease in mean count/gram for APC @ 35°C and APC @ 20°C; however, the overall microbiological profile of product produced during both phases was indicative of good manufacturing procedures.

Cooked Sausage plant 2 (CS 2)

Table 33 shows geometric means for the six quantitative microbiology factors at the different sampling points in CS 2 during Phases I and III. It also relates the sampling points to the generic HACCP Cooked Sausage model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels of incoming raw material were low. The cooking process further reduced the levels of microorganisms. The levels of microorganisms in the final product were similar to those just after cooking and chilling, indicating good handling procedures during peeling and packaging. The overall

TABLE 33: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III COOKED SAUSAGE PLANT 2

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
Formulation*						
Chop/Blend/Emulsify*						
Stuffing						
	114,000	337,000	279	5	2	4
	52,100	184,000	50	3	4	2
Cook/Smoke*						
Showering						
Chill/Storage*						
	37	27	1	1	1	1
	30	35	1	1	1	1
Peeling*						
Packaging*						
	35	46	1	1	1	1
	24	23	1	1	1	1
Storage*						
Shipping/Distribution						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

microbiological profile of the final product in both Phases I and III was indicative of good processing procedures, and there was little practical difference between them.

Table 34 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III. There were greater numbers of samples for final product because duplicate samples were collected each sampling day in this plant. Only APC @ 35°C and APC @ 20°C showed appreciable percent positives in final product (see Pct values). Figures 13 and 14 display the APC @ 35°C and 20°C distributions. Little increase in microbial levels following cooking was noted in Phase I and Phase III.

Run charts for the six quantitative microbiology factors in final product are presented in Figure 15. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C and APC @ 20°C, if appropriate. There are runs of points below the centerline in Phases I and III for APC @ 35°C (starting on days 10 and 486) and for APC @ 20°C (starting on days 15 and 486); there are runs above the centerline in Phase I for both factors (starting on day 121). This variation indicates an unstable process.

Results for *Listeria* species swabs were as follows: 2 of 51 positive in Phase I, and 2 of 45 positive in Phase III. The occasional presence of *Listeria* species in environmental samples is not uncommon, but indicates the need to monitor cleaning and disinfection procedures closely.

The chemistry testing results of finished product in Phases I and III are displayed in Table 35.

The mean nitrite values for CS 2 were nearly the same in Phases I and III (40.6 ppm and 40.8 ppm, respectively) and significantly lower than the maximum allowable level of 156 ppm in the formulation of the product. The maximum values of 65 ppm and 52 ppm for Phases I and III, respectively, are also well below the maximum allowable limit. As explained in the discussions of CS 1, this wide variation is due to the relative instability of sodium nitrite. The Phases I and III percentages for brine show that CS 2 is within the normal range for cooked sausage product.

In summary, the HACCP microbiological assessment in Cooked Sausage Plant CS 2 showed process instability for APC @ 35°C and APC @ 20°C; however, the overall microbiological profile of product produced during both phases was indicative of good manufacturing procedures.

TABLE 34: SUMMARY STATISTICS FOR MICROBIAL FACTORS COOKED SAUSAGE PLANT 2

Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	50	100.0	5.1	.75	51	86.3	1.8	.51	102	82.4	1.8	.42
	3	46	100.0	4.7	.95	47	95.7	1.5	.56	90	90.0	1.5	.42
APC @20°C	1	50	100.0	5.5	.73	51	76.5	1.9	.53	102	89.2	1.8	.53
	3	46	100.0	5.3	.81	47	91.5	1.7	.60	90	85.6	1.5	.45
Coliforms	1	50	98.0	2.5	.64	51	0.0	1.7		102	0.0	1.0	
	3	46	76.1	2.2	.59	47	0.0			90	0.0		
E. coli	1	50	48.0	1.5	.37	51	0.0			102	0.0		
	3	46	30.4	1.7	.48	47	0.0			90	0.0		
S. aureus	1	50	14.0	2.3	.56	51	2.0	1.3		102	2.0	1.0	.28
	3	46	28.3	2.2	.30	47	0.0			90	0.0	1.0	
GFAs	1	50	44.0	1.3	.46	51	15.7	1.3	.00	102	5.3	1.0	.00
	3	46	26.1	1.2	.39	47	2.1	1.2		90	1.2	1.0	

Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

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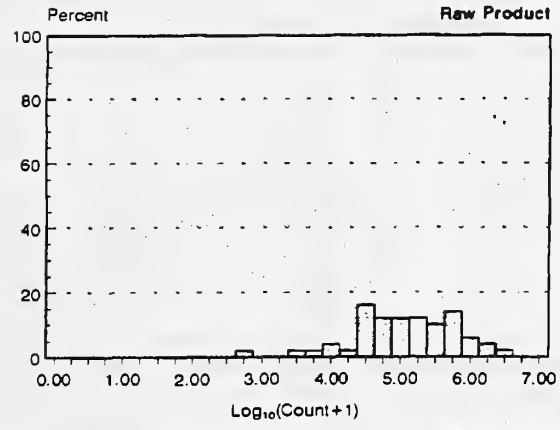
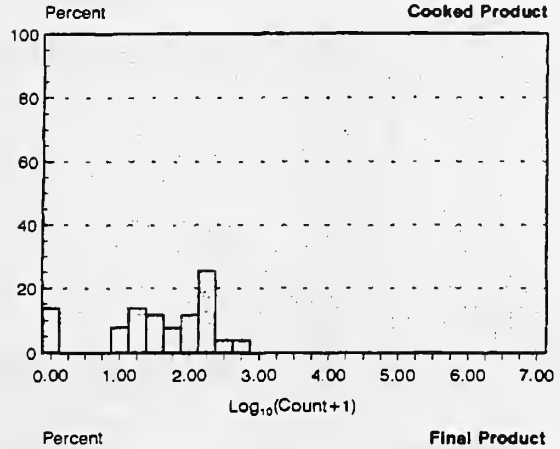
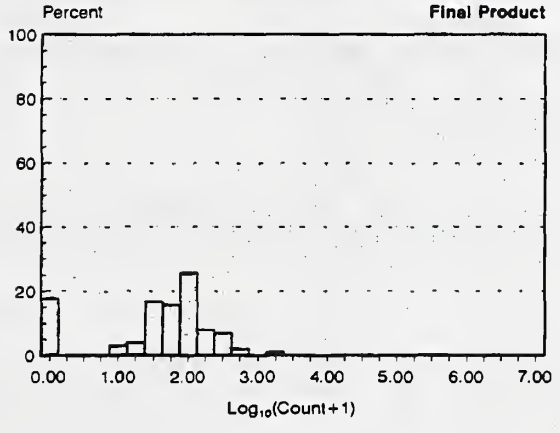
Figure 13. APC@35°C Distributions - Plant CS2

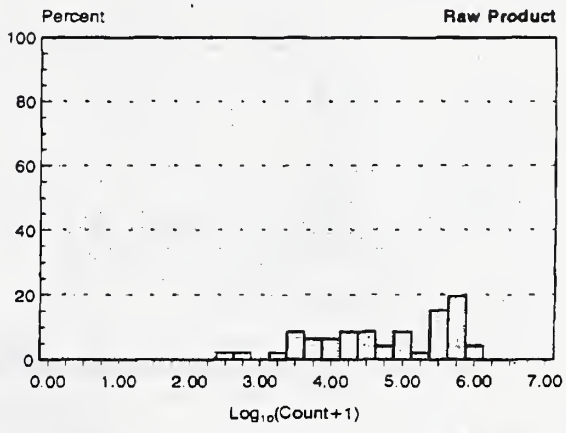
Phase 1

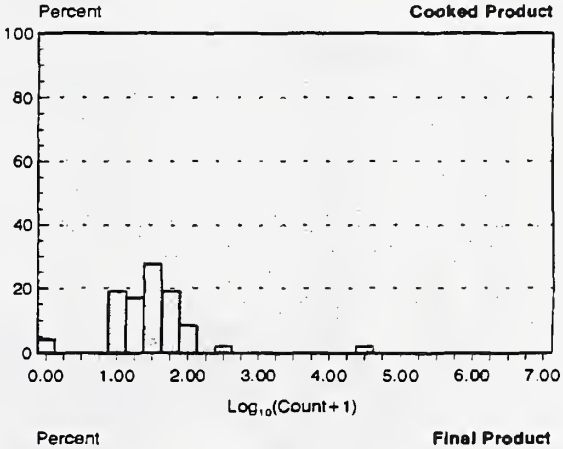






Phase 3





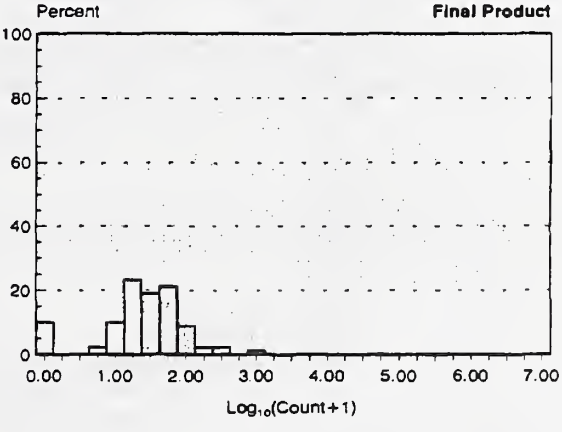
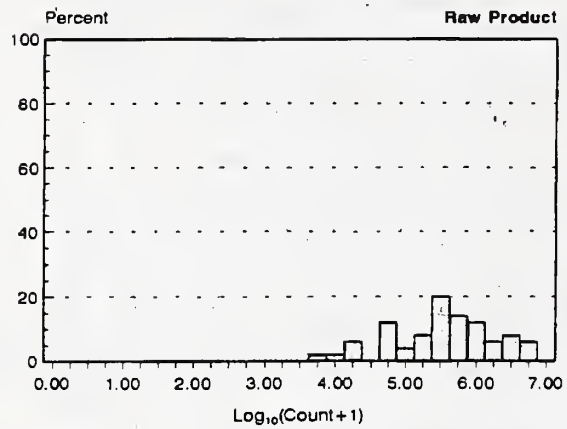
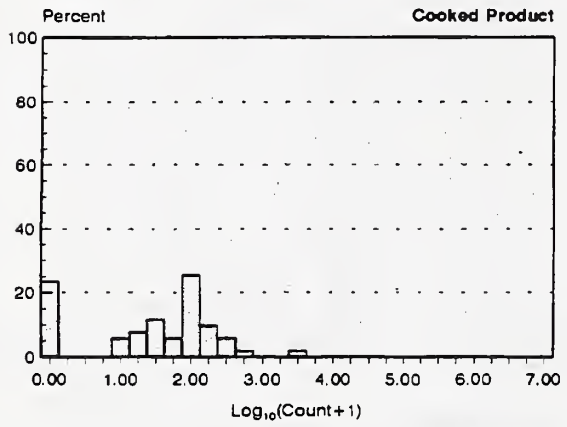
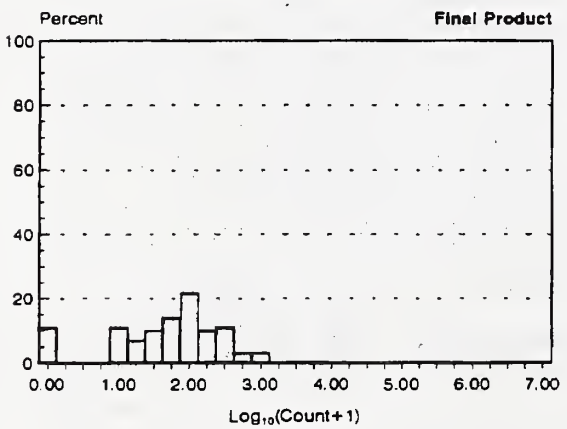


Figure 14. APC@20°C Distributions - Plant CS2

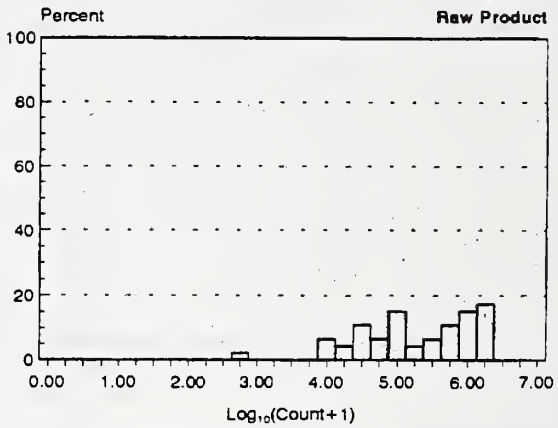
Phase 1

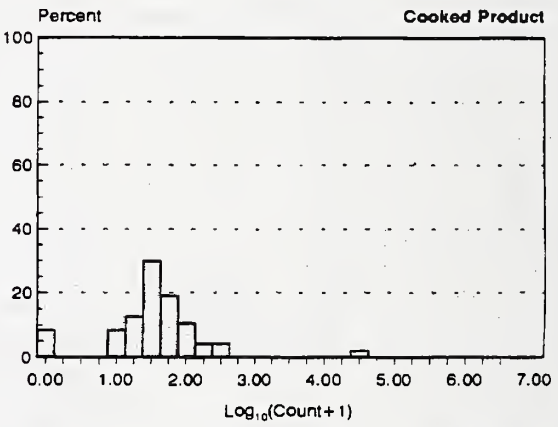






Phase 3





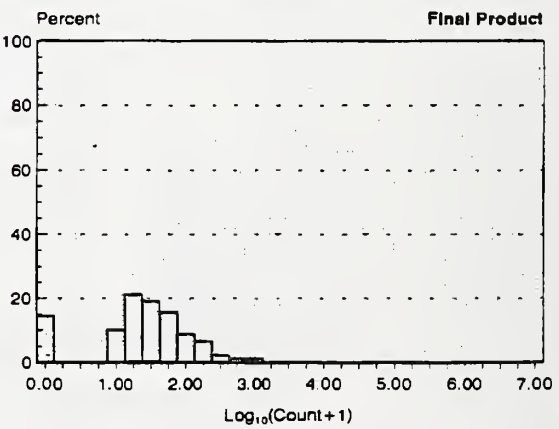
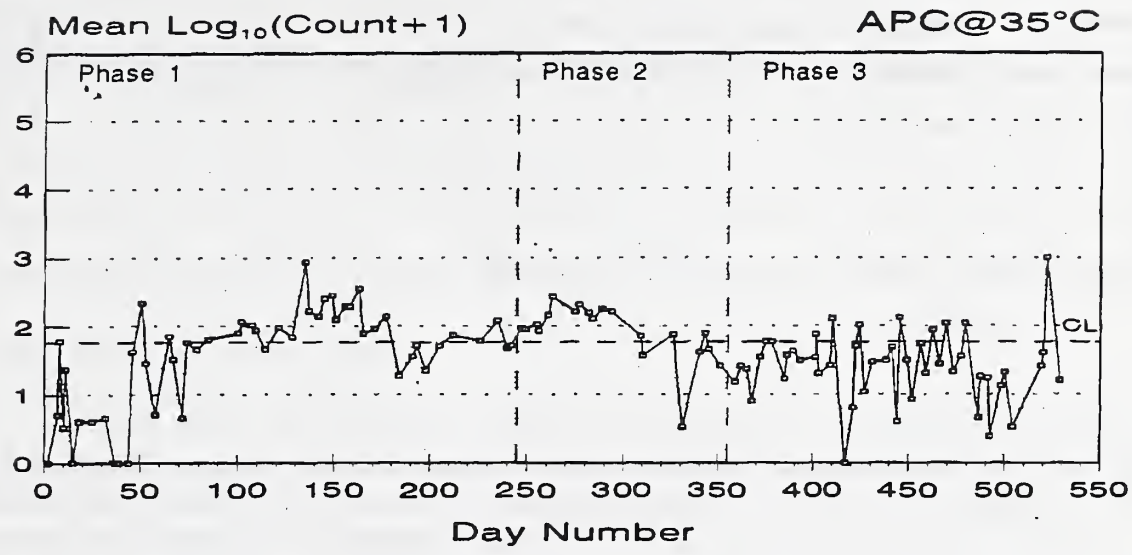
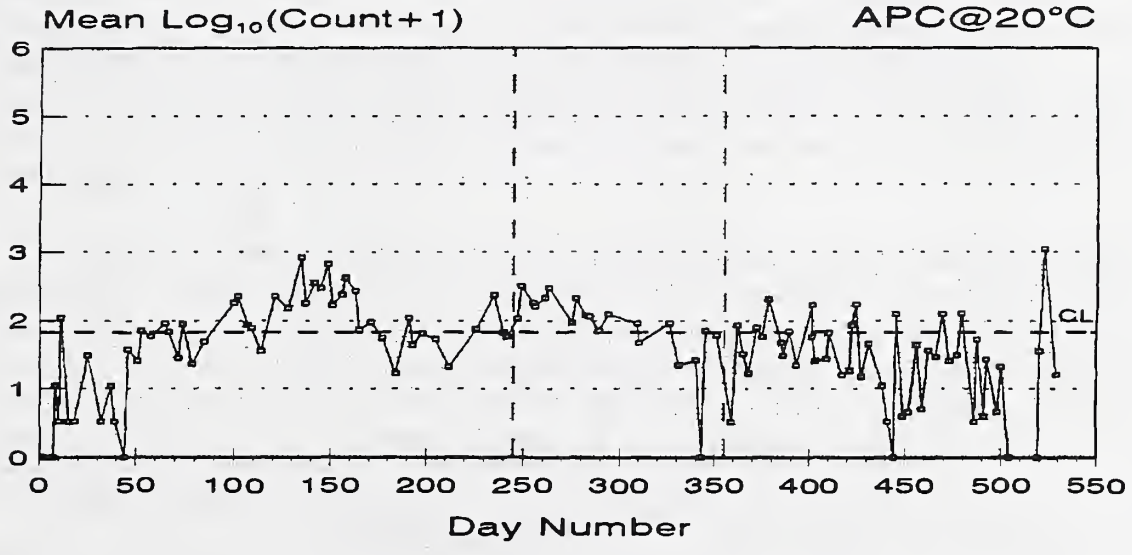
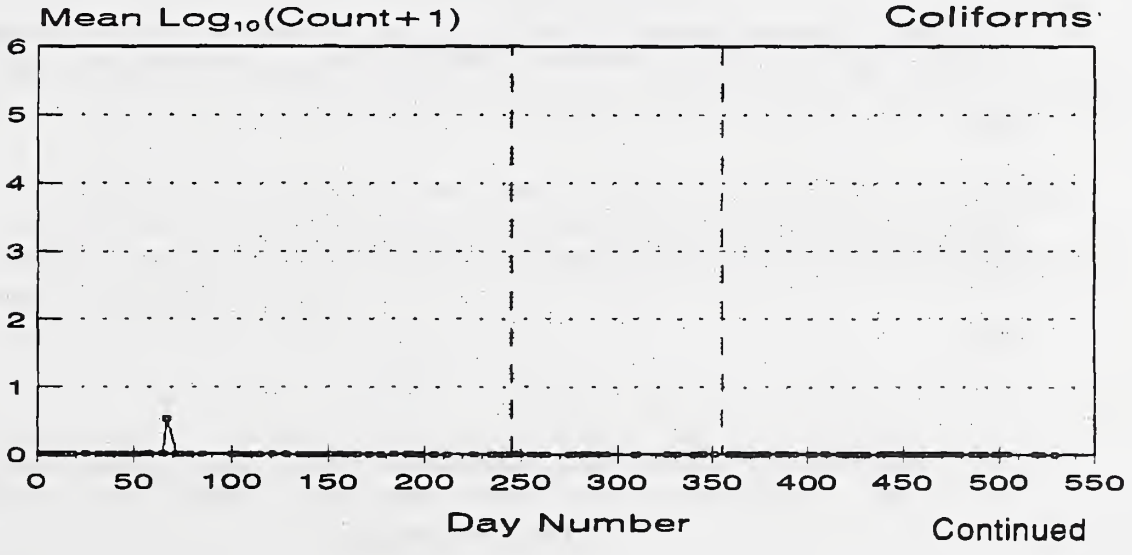


Figure 15. Run Charts for Microbiology Data
Cooked Sausage Plant 2 - Final Product

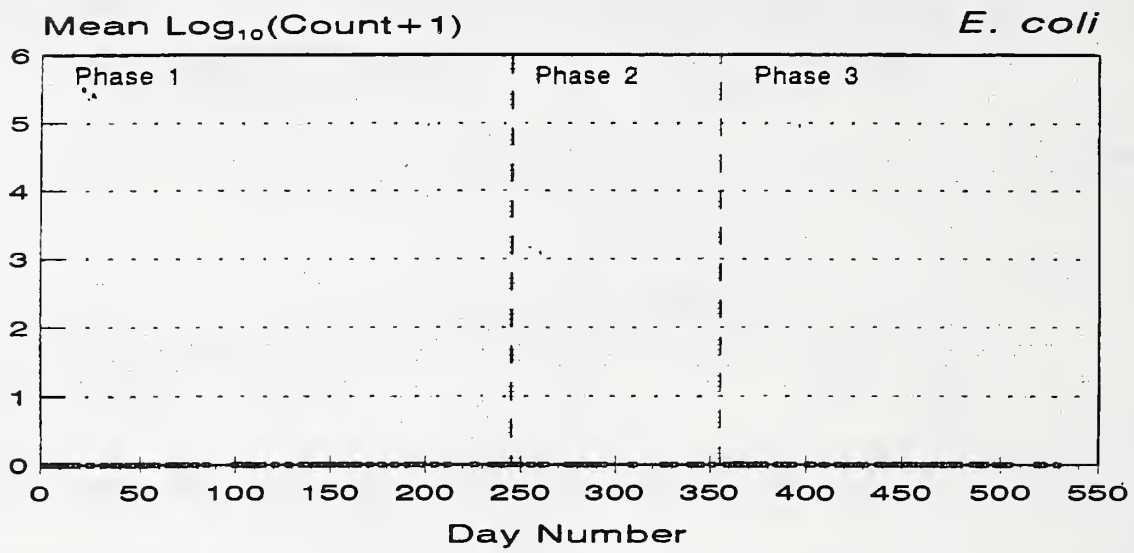


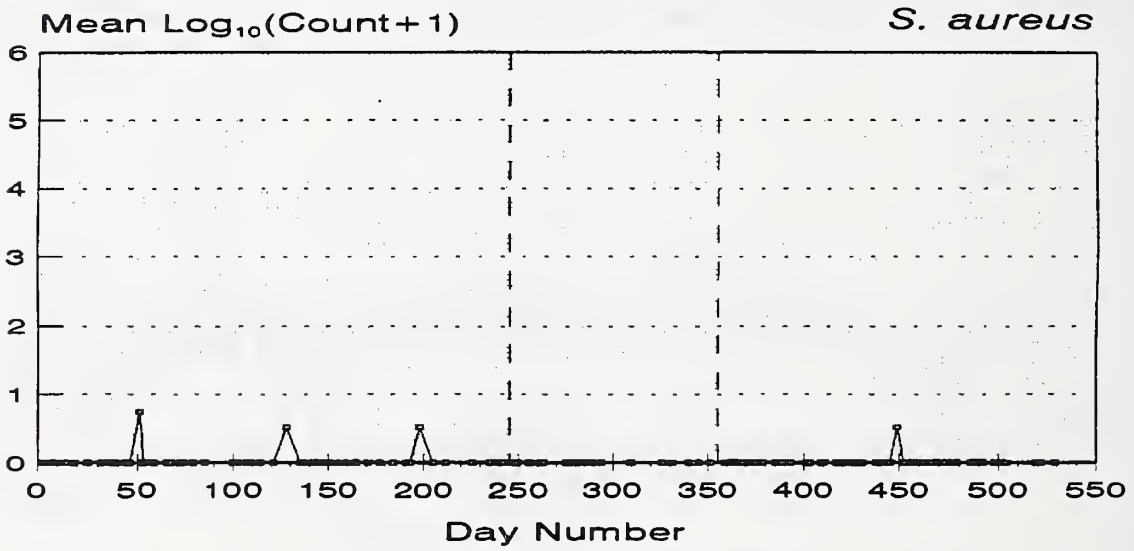




Continued

Figure 15 (continued). Run Charts for Microbiology Data
Cooked Sausage Plant 2 - Final Product





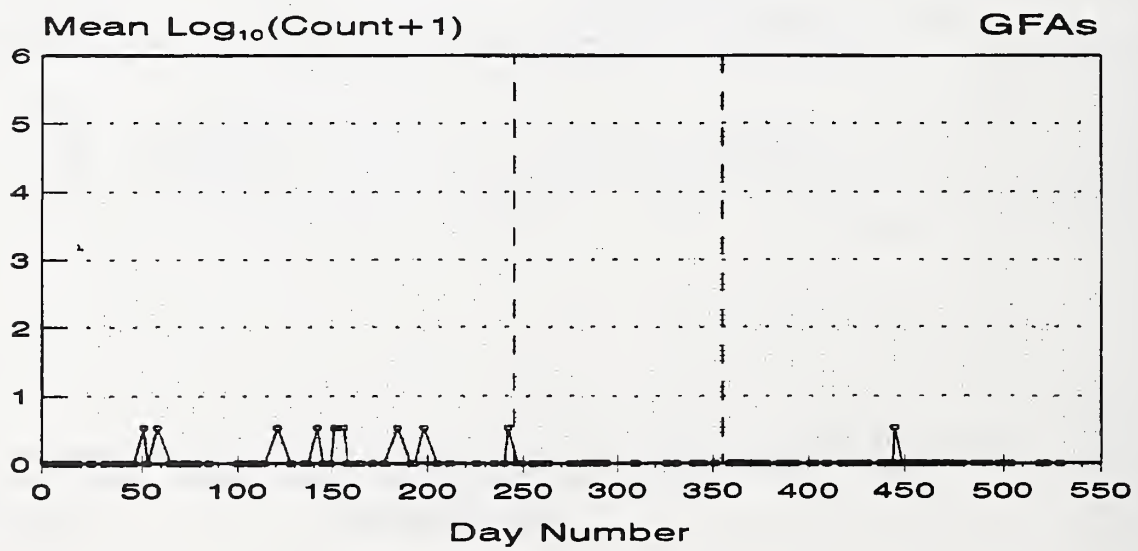


TABLE 35: NITRITE AND BRINE CHEMISTRY TESTING RESULTS FOR CS 2

Analyte	Phase	N	Mean	Minimum	Maximum
Nitrite	1	75	40.6	16.0	65.0
	3	14	40.8	27.0	52.0
Brine	1	75	4.2	3.7	4.8
	3	14	4.0	3.9	4.2

Cooked Sausage plant 3 (CS 3):

Table 36 shows geometric means for the six quantitative microbiology factors for CS 3 at the different sampling points during Phases I and III. It also relates the sampling points to the generic HACCP Cooked Sausage model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels of incoming raw material were low. The cooking process further reduced the levels of microorganisms. The levels of microorganisms in the final product were similar to those just after cooking and chilling, indicating good handling procedures during peeling and packaging. The overall microbiological profile of the final product in both Phases I and III was indicative of good processing procedures and there was little practical difference between them.

Table 37 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III. There were greater numbers of samples for final product because duplicate samples were collected each sampling day in this plant. Only APC @ 35°C and APC @ 20°C showed appreciable percent positives in final product (see Pct values). Figures 16 and 17 display the APC @ 35°C and 20°C distributions. Little increase in microbial levels following cooking was noted in Phase I and Phase III.

Run charts for the six quantitative microbiology factors in final product are presented in Figure 18. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C and APC @ 20°C. There are runs of points below the centerline in Phase I and III for APC @ 35°C (starting on days 86 and 227) and for APC @ 20°C (starting on days 86 and 248); there are runs above the centerline in Phase I for both factors (starting on day 43). This variation indicates an unstable process.

Results for *Listeria* species swabs were as follows: 0 of 69 positive in Phase I, and 1 of 47 positive in Phase III. The occasional presence of *Listeria* species in environmental samples is not uncommon, but indicates the need to monitor cleaning and disinfection procedures closely.

TABLE 36: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III COOKED SAUSAGE PLANT 3

Process Step	APC @ 35°C	APC @ 20°C	Coliforms	*E. coli*	*S. aureus*	GFAs
Receiving						
Storage						
Preparation						
Formulation*						
Chop/Blend/Emulsify*						
Stuffing						
	9,830	18,100	9	2	2	5
—	7,560	33,500	6	2	5	3
Cook/Smoke*						
Showering						
Chill/Storage*						
	30	19	1	1	1	1
—	14	10	1	1	1	1
Peeling*						
Packaging*						
	27	22	1	1	1	1
—	12	7	1	1	1	1
Storage*						
Shipping/Distribution						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. All values are reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=10) were assigned a value of 1 in computing the geometric mean.

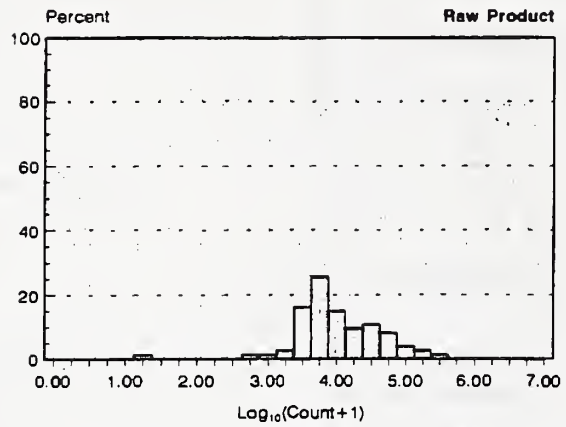
TABLE 37: SUMMARY STATISTICS FOR MICROBIAL FACTORS COOKED SAUSAGE PLANT 3

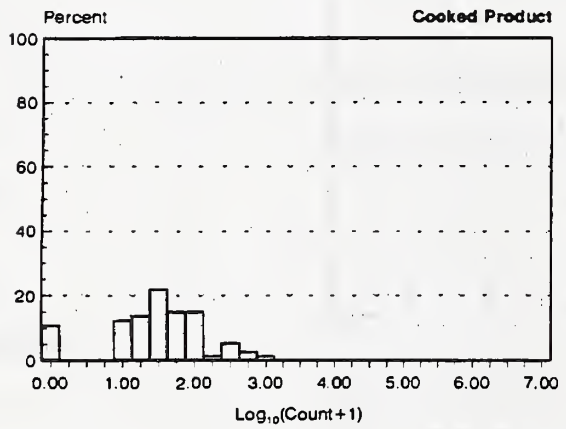
Microbial Factor	Phase	Raw Product				Cooked Product				Final Product			
		Num	Pct	Ave	Std	Num	Pct	Ave	Std	Num	Pct	Ave	Std
APC @35°C	1	74	100.0	4.0	.63	73	89.0	1.7	.49	144	87.5	1.6	.46
	3	32	100.0	3.9	.66	31	77.4	1.5	.38	66	74.2	1.4	.45
APC @20°C	1	74	100.0	4.3	.73	73	80.8	1.6	.49	144	78.5	1.7	.47
	3	32	100.0	4.5	.78	31	71.0	1.4	.43	66	62.1	1.4	.47
Coliforms	1	74	59.5	1.6	.53	73	0.0			144	0.7	1.0	
	3	32	53.1	1.5	.42	31	0.0			66	0.0		
E. coli	1	74	24.3	1.3	.41	73	0.0			144	0.0		
	3	32	31.3	1.1	.28	31	0.0			66	0.0		
S. aureus	1	74	12.2	2.3	.29	73	1.4	1.0		144	0.0		
	3	32	31.3	2.3	.56	31	0.0			66	0.0		
GFAs	1	74	51.4	1.3	.53	73	6.8	1.2	.45	144	6.2	1.1	.33
	3	32	37.5	1.3	.45	31	0.0			66	0.0		

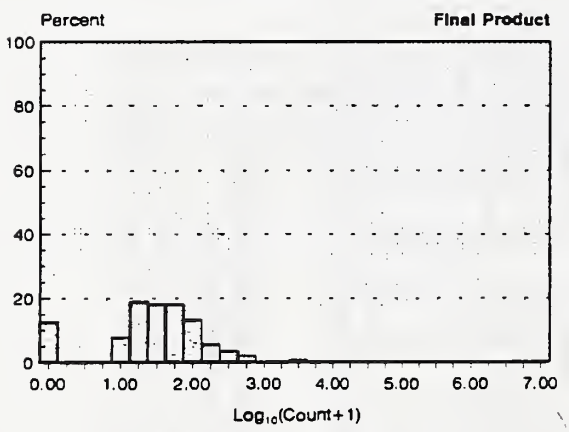
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

Figure 16. APC@35°C Distributions - Plant CS3

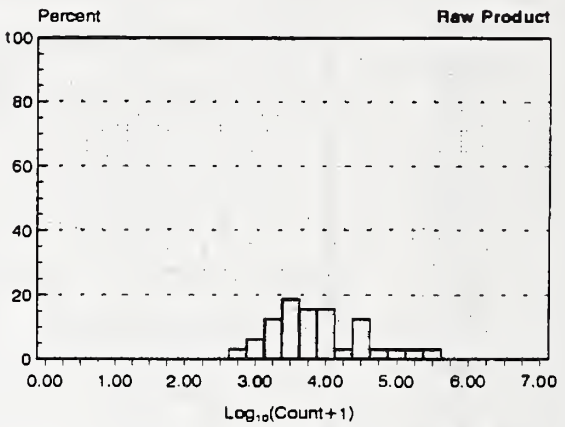
Phase 1

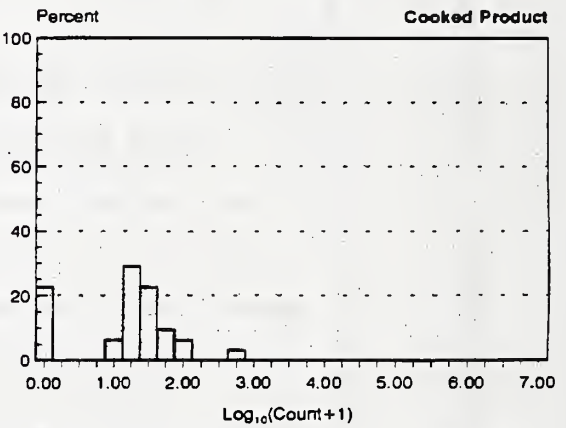






Phase 3





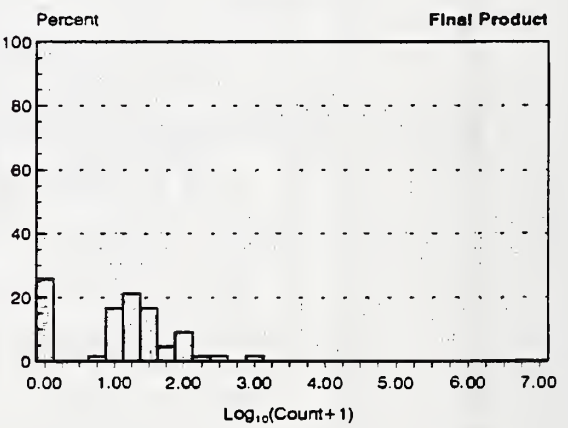
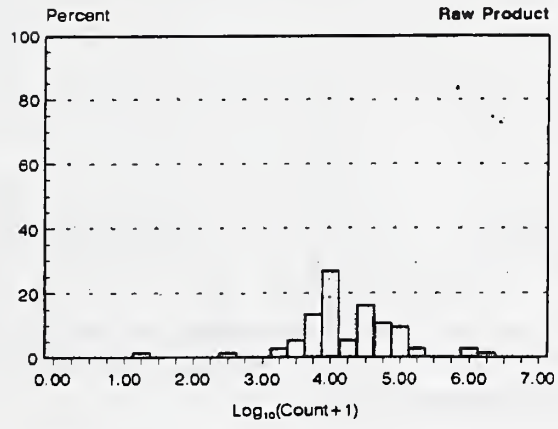
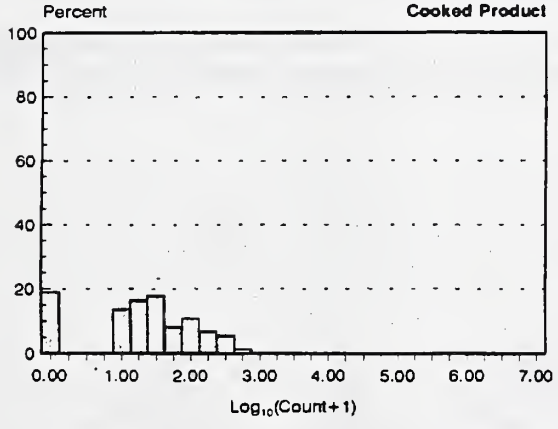
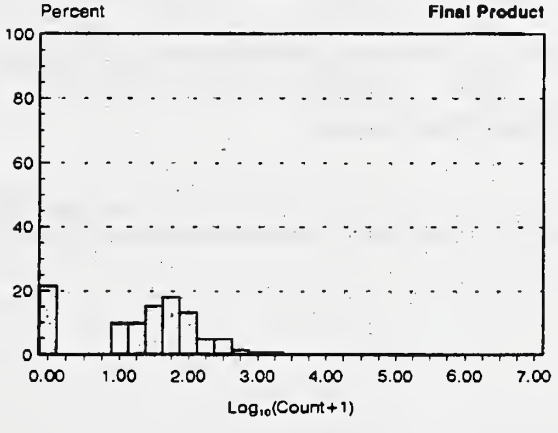


Figure 17. APC@20°C Distributions - Plant CS3

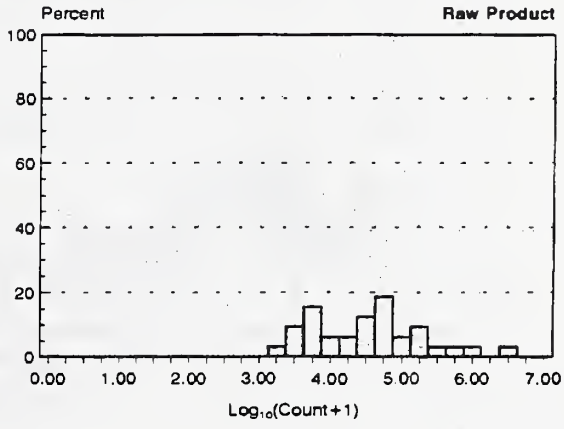
Phase 1

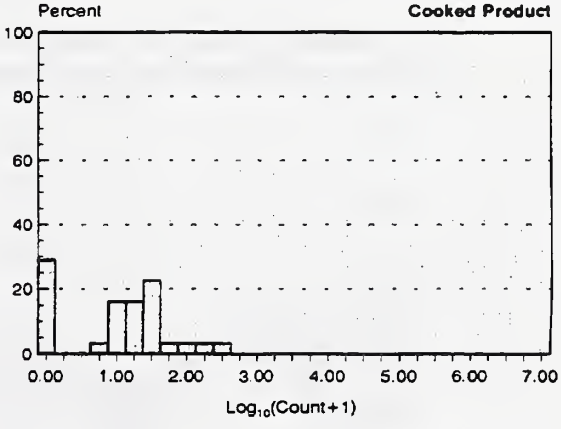






Phase 3





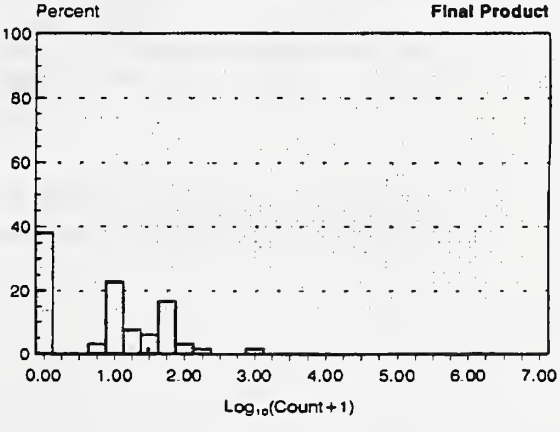
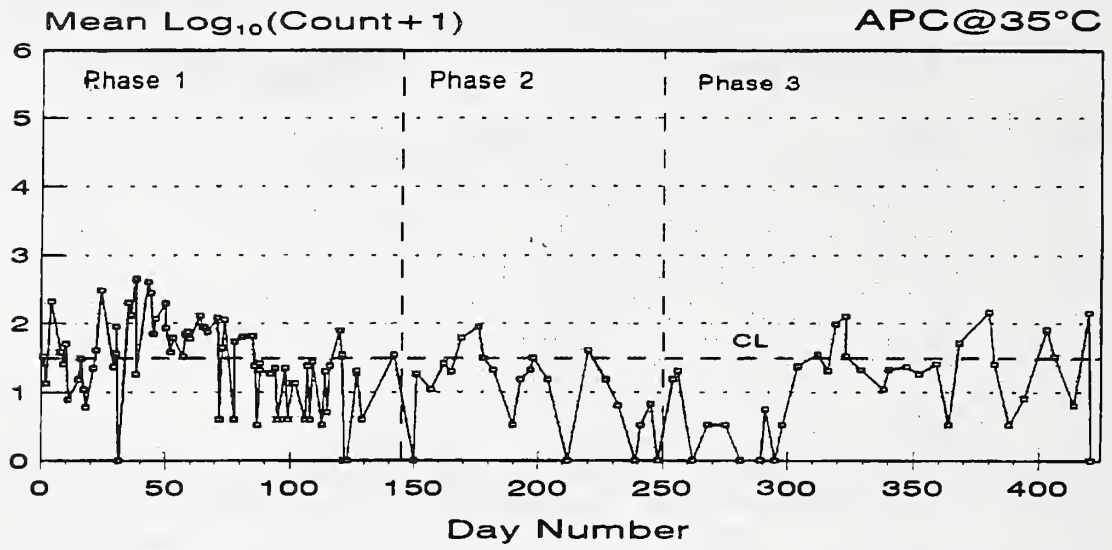
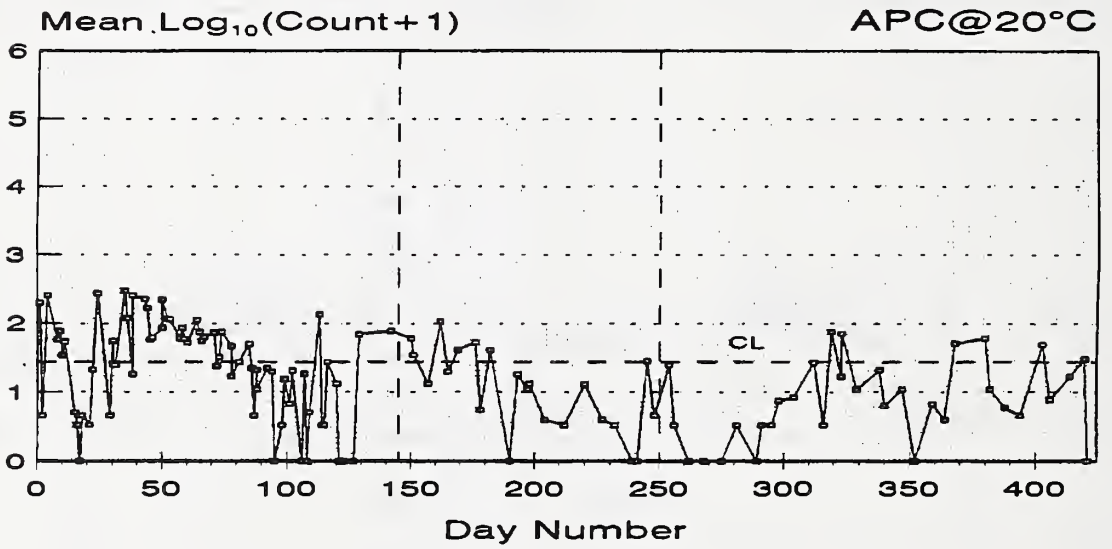
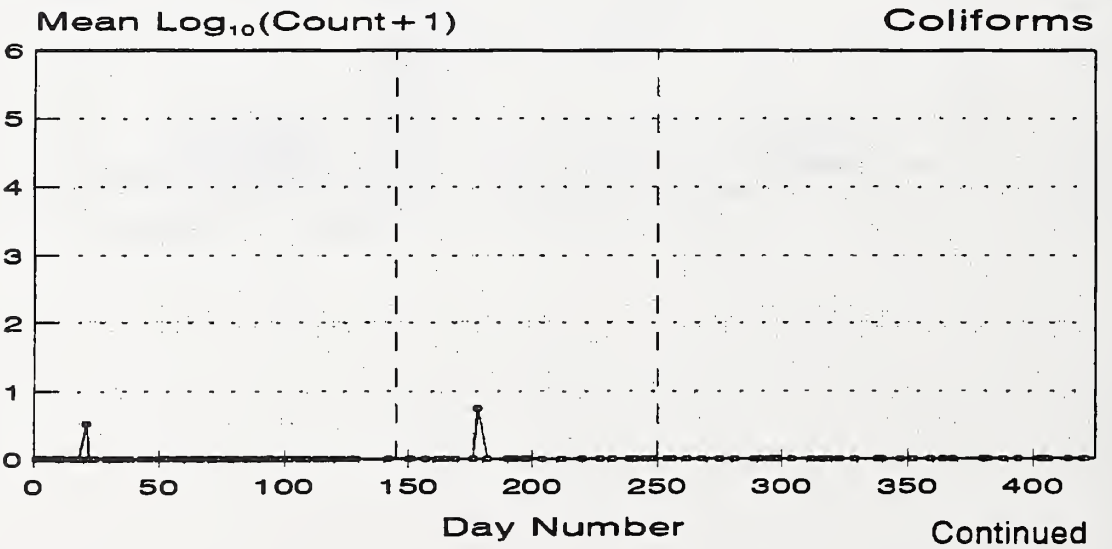


Figure 18. Run Charts for Microbiology Data
Cooked Sausage Plant 3 - Final Product

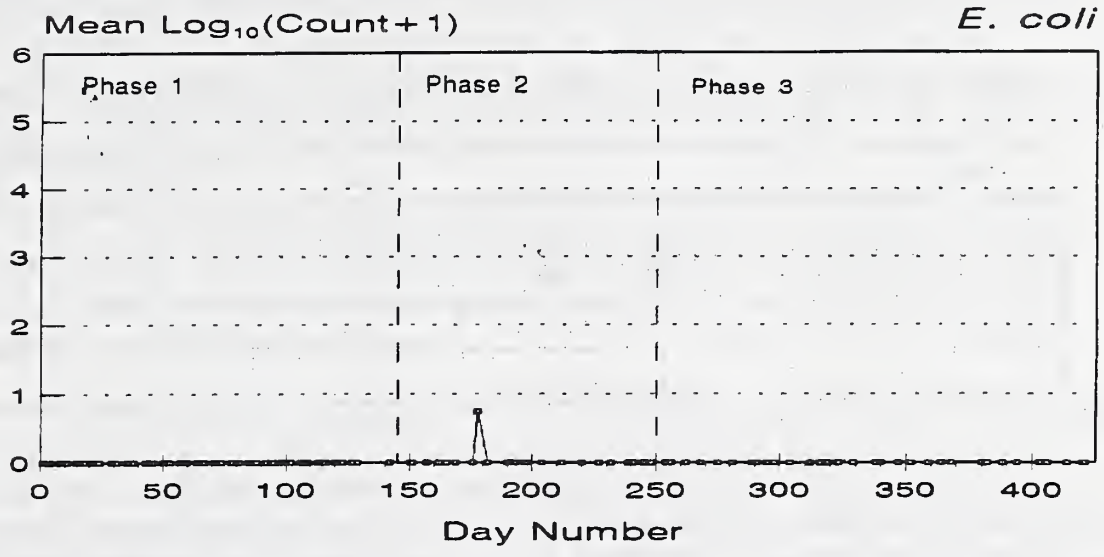


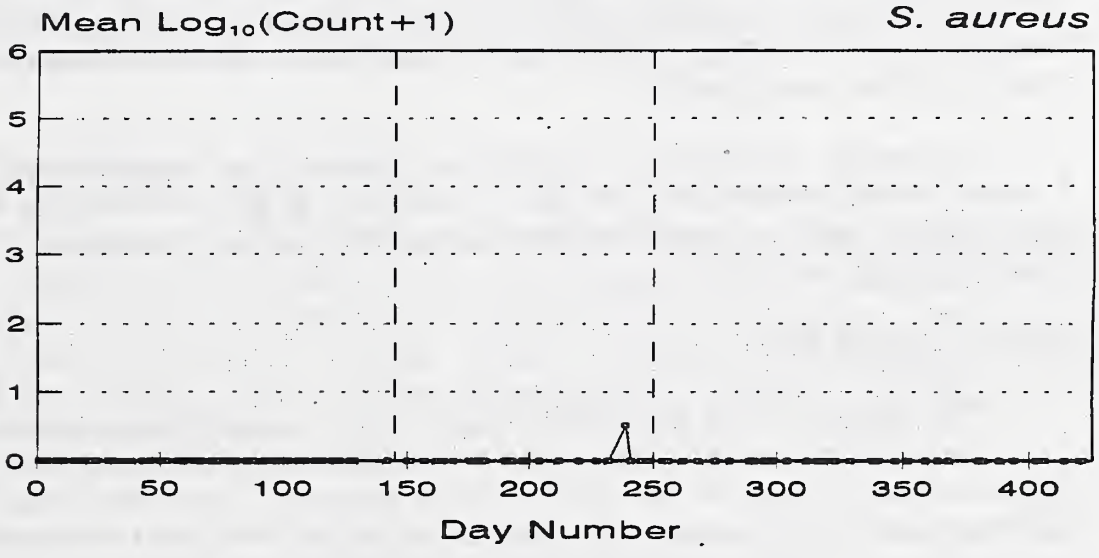


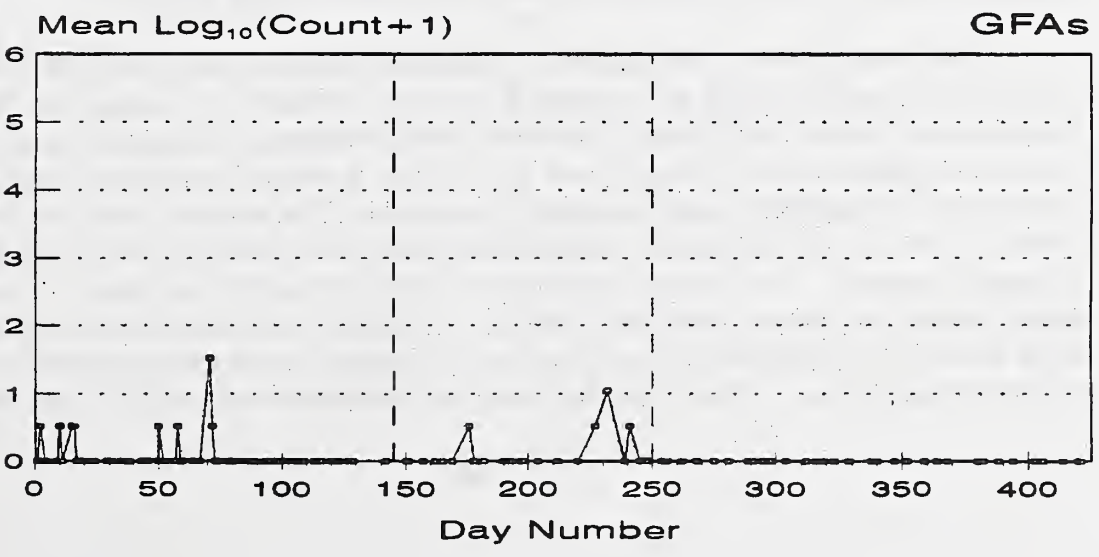


Continued

Figure 18 (continued). Run Charts for Microbiology Data.
Cooked Sausage Plant 3 - Final Product







The chemistry testing results of finished product for nitrite and brine in Phases 1 and III are displayed in Table 38.

TABLE 38: NITRITE AND BRINE CHEMISTRY TESTING RESULTS FOR CS 3

Analyte	Phase	N	Mean	Minimum	Maximum
Nitrite	1	74	48.5	16.0	83.0
	3	48	33.9	6.0	57.0
Brine	1	74	3.4	3.0	4.1
	3	48	3.4	3.2	3.7

As seen in Table 38, CS 3's mean nitrite values for both Phase I and III are well below the maximum allowable level of 156 ppm and in the formulation of the product. The nitrite maximum value for Phase III (57.0 ppm) was lower than the Phase I value of 83.0 ppm. As previously discussed for CS 1 and CS 2, these ranges are due to the instability of sodium nitrite. The brine percentages for both phases are within the normal range for cooked sausage product.

In summary, the HACCP microbiological assessment in Cooked Sausage Plant CS 3 showed process instability for APC @ 35°C and APC @ 20°C; however, the overall microbiological profile of product produced during both phases was indicative of good manufacturing procedures.

Poultry Slaughter Plants:

The quantitative data for Poultry Slaughter plants included the six microbiology factors discussed in Chapter II. For all six factors, samples were collected at four different control points in the process: (1) before scalding; (2) after hock cutting; (3) after final wash; and (4) after carcass chill. Results for the first five factors were reported in counts per gram; results for *Salmonella* were reported as counts per bird.

The sampling sites were purposely selected to bracket (before and after) certain critical control points during the processing of broiler chickens. In contrast to the production of cooked, refrigerated foods and cooked sausages, no single critical control point during this production process can be relied on to assure the destruction of the microorganisms generally associated with live broilers. The sampling sites are depicted in Tables 39, 41 and 43 in relation to both the critical control points and other steps in the production process. The mean microbiological levels for each of the factors at each of the sampling sites are shown in the same tables. The values in the tables prior to scalding show the microbiological condition of the incoming birds at the earliest possible time in the production process. The values following the tables show the effect of the various

other process steps on the microbiological condition. In these tables, as indicated a value of one was assigned to samples which were negative to facilitate the calculation of the geometric mean. These tables show the relative levels of each microbiological factor at the various stages in the production process and present what is known as the "microbiological profile" of the production process. Tables 40, 42, and 44 present the percent of samples testing positive for each of the microbiological factors and the log average level for each.

One chemistry factor, chlorine in processing water was included. Chlorine in chiller water was tested as a possible explanatory variable in case of process control failures. Values were in units of 10 ppm (i.e., 0 ppm, 10 ppm, 20 ppm, etc.). The maximum permitted level is 50 ppm.

The plan to collect sample sets on 30 to 50 different days during both the baseline and operational phases (Phases I and III) was fulfilled for all three poultry slaughter plants. The results were analyzed, as outlined in the evaluation plan, to check each plant's ability to control its process and to compare characteristics of product produced in Phases I and III. Results are discussed separately for each plant. Results for microbiology and chemistry factors from Phase I were shared with the plants at the beginning of Phase II, and results from Phase II were shared as they became available.

Poultry Slaughter plant 1 (PS 1):

Table 39 shows geometric means for the six quantitative microbiology factors at the different sampling points for PS 1 during Phases I and III. It also relates the sampling points to the generic HACCP Poultry Slaughter model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels were high for incoming birds but each successive processing step reduced the microbial population on the birds.

TABLE 39: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III POULTRY SLAUGHTER PLANT 1

Process Step	APC @ 35°C	Coliforms	*E. coli*	*S. aureus*	GFAs	Salmonella
Receiving*						
Hanging						
Stunning						
Killing						
Bleeding	2,180,000	1,270	632	5	234	1
| —	3,890,000	1,330	624	2	178	2
Scalding*						
Picking						
Singeing						
Remove Head						
Washing						
Hock cutter	9.060	234	148	10	59	1
| —	6,560	130	69	2	7	1
Transf/rehang						
Oil Sac cut						
Vent/etc.*						
Presenting						
Inspection						
Helper						
Liver/Heart						
Gut cutter						
Gizzard						
Cropping						
Break Neck						
Remove Lung						
Trimmer						
House Check						
Final Wash*	1,950	17	10	9	10	1
| —	2,010	23	13	24	3	1
Neck cutter						
Carcass chill*	185	3	2	1	2	1
| —	347	7	4	4	2	1
Sort/etc.						
Package/etc.						
Storage/Dist*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. *Salmonella* was reported on a per bird basis; other values were reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=1) were assigned a value of 1 in computing the geometric mean.

Table 40 gives more detailed summary statistics for the same factors at the four sampling points during Phases I and III.

Figures 19 - 24 show the distribution for APC @ 35°C, coliforms, *E. coli*, *S. aureus*, GFA, and *Salmonella*. The results generally show decreases in all factors as the product moves through successive stages of processing. Phase I and Phase III results are similar.

Run charts for the six quantitative microbiology factors are presented in Figure 25. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C , coliforms, and GFAs. For APC @ 35°C and coliforms, there are runs of points above the centerline in Phase III (starting on days 288 and 341 for APC @ 35°C and on days 285 and 358 for coliforms). This variation indicates that a shift to higher process mean count/gram occurred in Phase III for these factors. Figure 24 and Table 40 show that *Salmonella* results for Phase III tended to he higher than those for Phase I. This difference was to be expected, since the *Salmonella* counts for the incoming birds in Phase III were higher than in Phase I.

Percent positive *Salmonella* was proposed to be used for process control verification; therefore percent positives for Phases I and III were compared. The difference, 3.5 percent vs 15.4 percent, was found to be statistically significant ($P<.05$).

The median chlorine levels were 30 ppm in Phase I and 20 ppm in Phase III. The chlorine level was lowered around day 250. This change may account in part for higher microbial levels in Phase III.

In summary, the HACCP microbiological assessment in Poultry Slaughter Plant PS 1 showed a shift to higher microbial levels and an increase in *Salmonella* in Phase III. However, the microbiological profile of the product produced during both phases was indicative of good manufacturing procedures.

Poultry Slaughter plant 2 (PS 2):

Table 41 shows geometric means for the six quantitative microbiology factors at the different sampling points in PS 2 during Phases I and III. It also relates the sampling points to the generic HACCP Poultry Slaughter model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels were high for incoming birds but, each successive step reduced the microbial population on the birds.

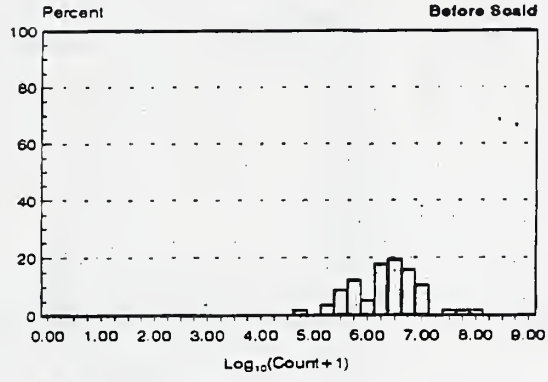
TABLE 40: SUMMARY STATISTICS FOR MICROBIAL FACTORS POULTRY SLAUGHTER PLANT 1

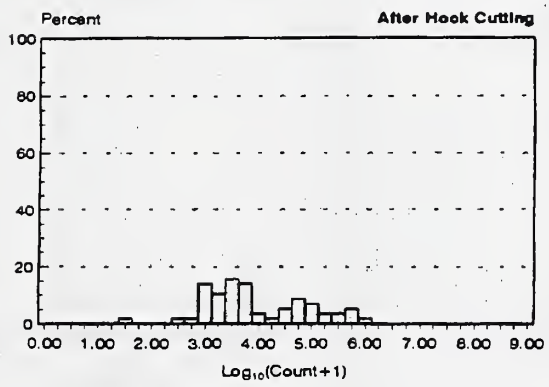
Microbial Factor	Phase	Num	Before Scald			After Hock Cut			After Final Wash			After Chill Tank		
			Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std
APC @35°C	1	57	100.0	6.3	.63	100.0	4.0	.96	100.0	3.3	.80	100.0	2.3	.56
	3	52	100.0	6.6	.47	100.0	3.8	.60	100.0	3.3	.58	100.0	2.5	.75
Coliforms	1	57	98.2	3.2	1.14	96.5	2.5	1.60	93.0	1.3	1.04	56.1	.8	.53
	3	52	100.0	3.1	.85	98.1	2.2	1.03	100.0	1.4	.92	84.6	1.0	.82
E. coli	1	57	94.7	3.0	1.25	94.7	2.3	1.57	80.7	1.3	1.07	45.6	.5	.47
	3	52	98.1	2.9	.94	96.2	1.9	1.04	94.2	1.2	.88	78.8	.8	.76
S. aureus	1	57	17.5	4.1	1.06	47.4	2.1	1.40	61.4	1.5	1.26	19.3	.9	1.12
	3	52	9.6	3.0	.65	30.8	1.0	.84	78.8	1.8	1.04	51.9	1.2	1.11
GFAs	1	57	93.0	2.5	1.10	86.0	2.1	1.28	78.9	1.3	.86	54.4	.5	.63
	3	52	92.3	2.4	.97	73.1	1.2	1.03	73.1	.7	.66	50.0	.8	.76
Salmonella	1	57	15.8	.7	.80	10.5	.2	.24	7.0	1.2	.67	3.5	.2	.22
	3	52	32.7	.8	.90	21.2	.4	.57	13.5	1.1	.98	15.4	.8	1.00

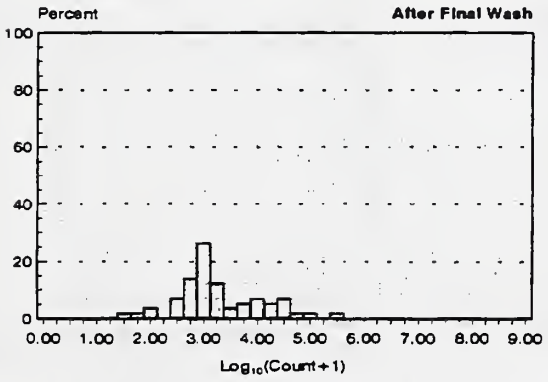
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

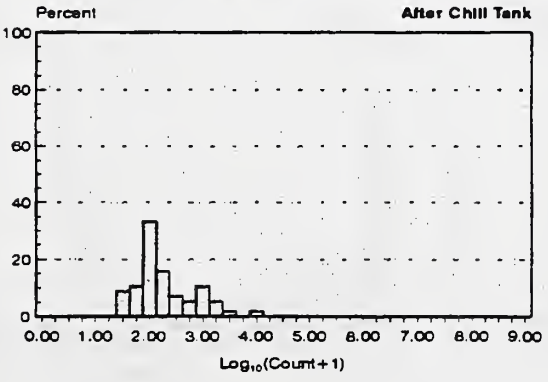
Figure 19. APC@35°C Distributions - Plant PS1

Phase 1

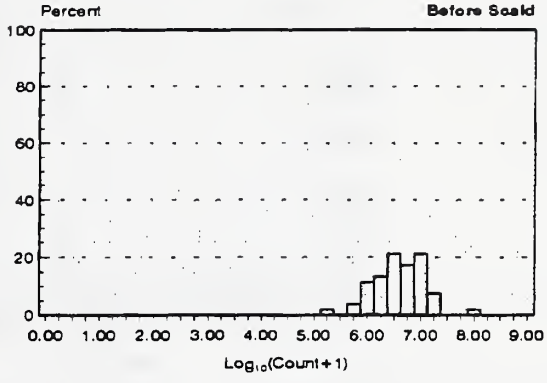


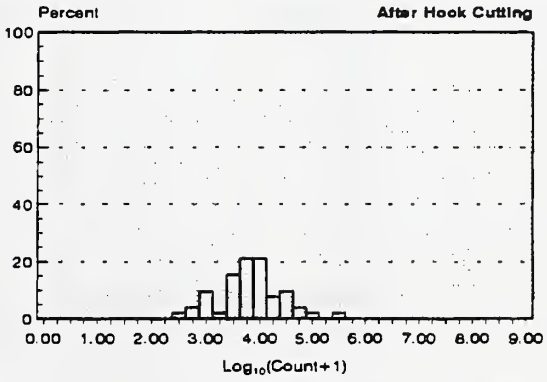


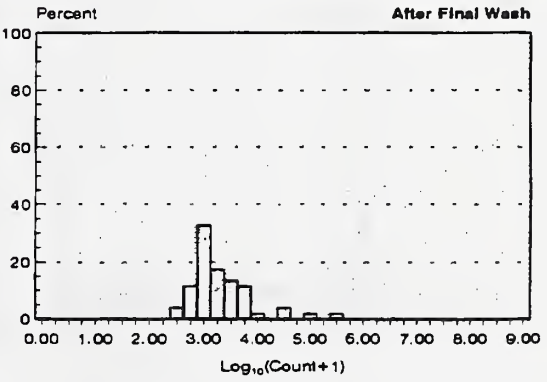




Phase 3







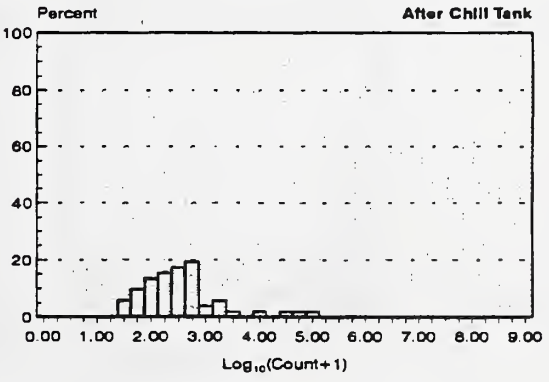
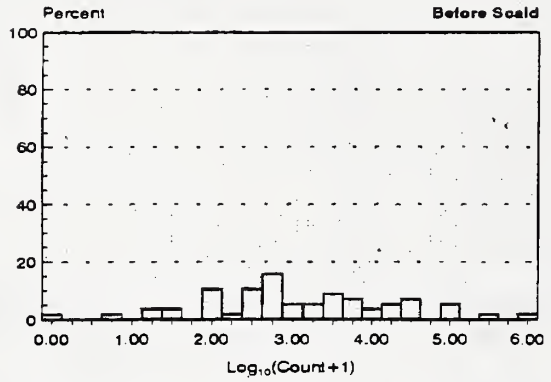
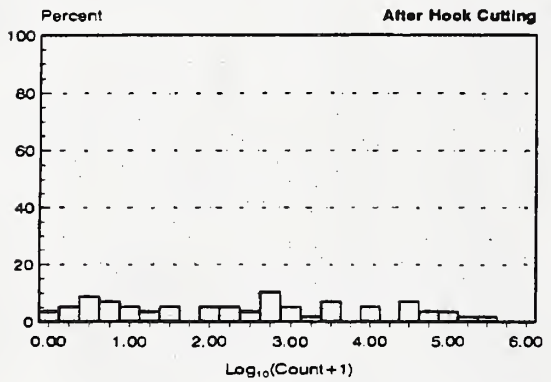
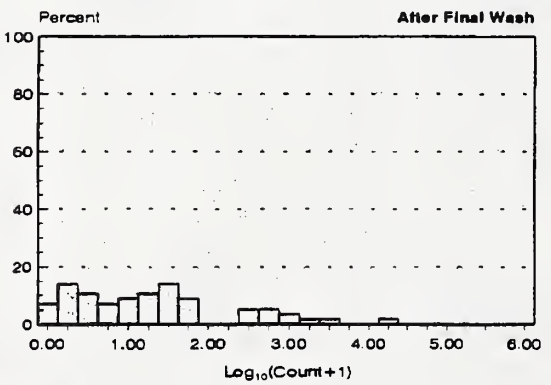


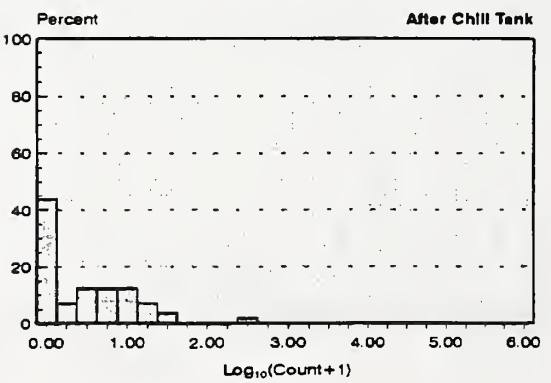
Figure 20. Coliform Distributions - Plant PS1

Phase 1

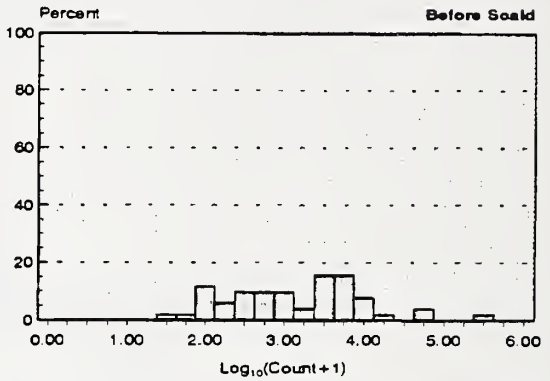


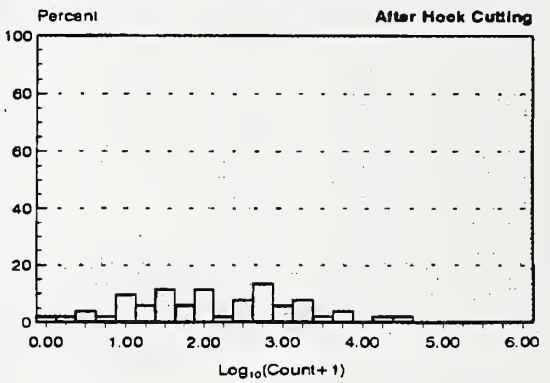


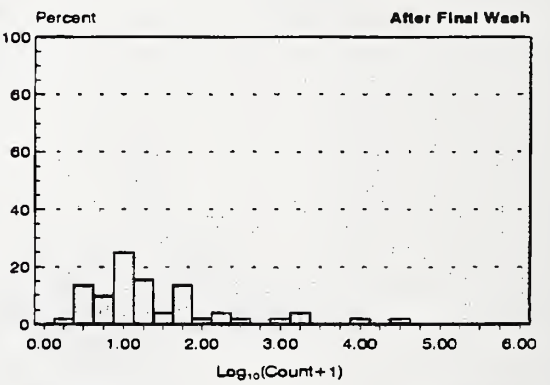




Phase 3







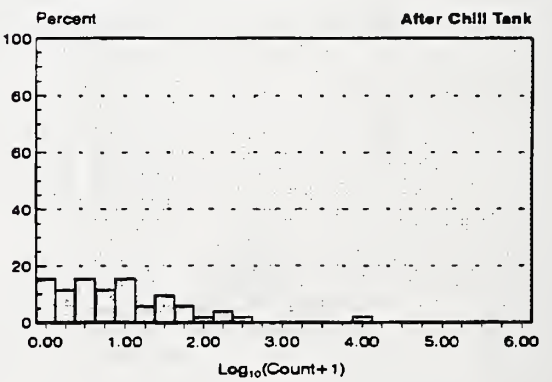
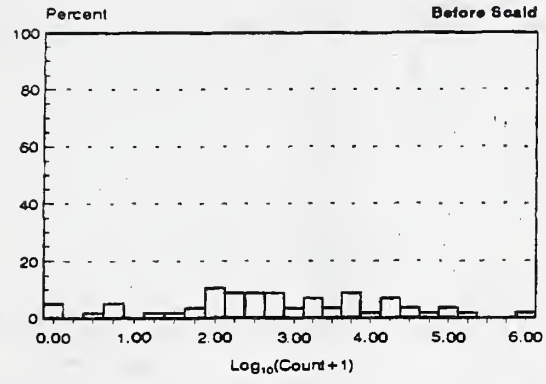
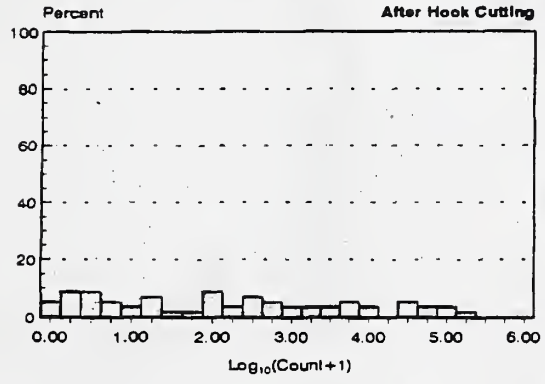
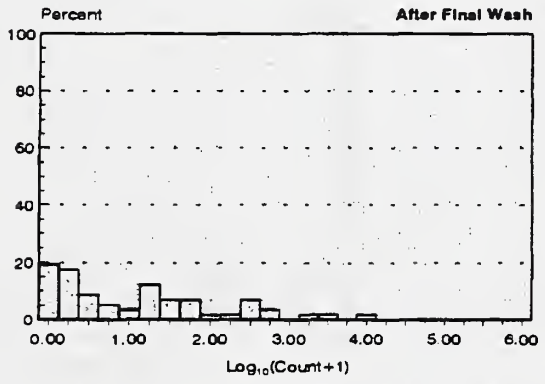


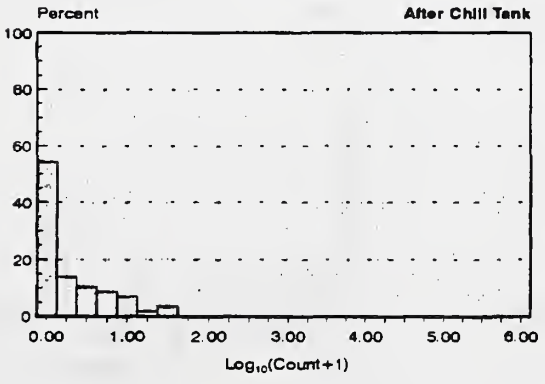
Figure 21. *E. coli* Distributions - Plant PS1

Phase 1

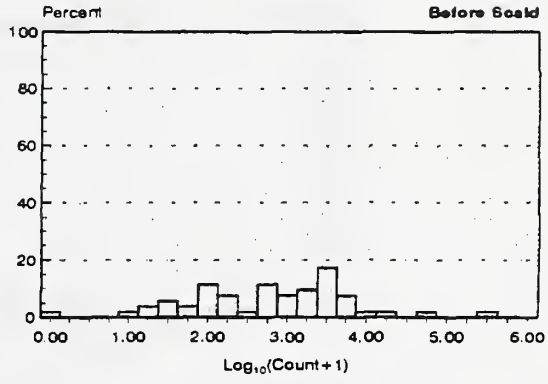


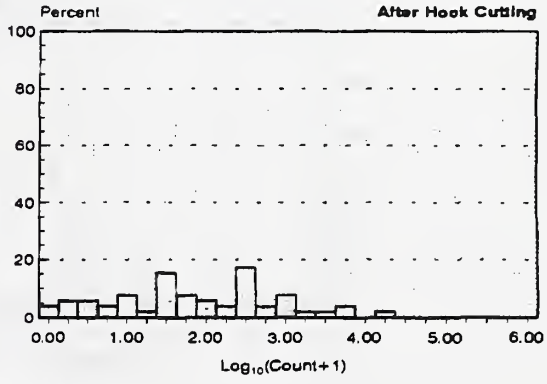


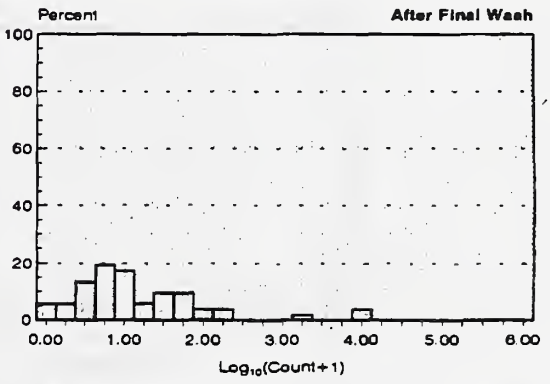




Phase 3







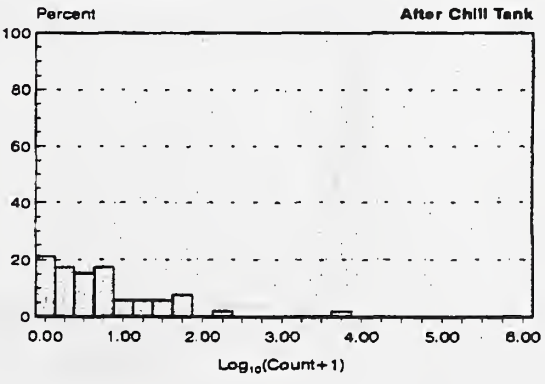
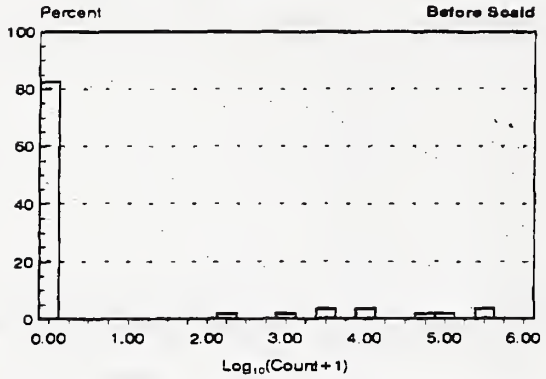
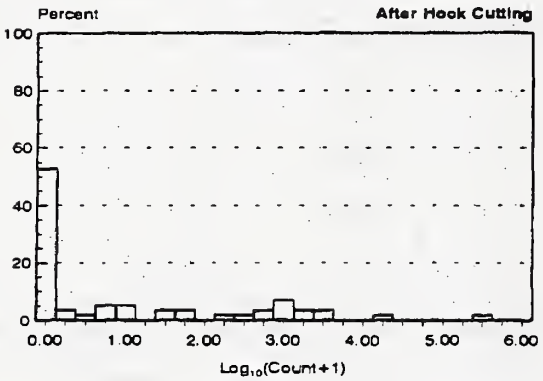
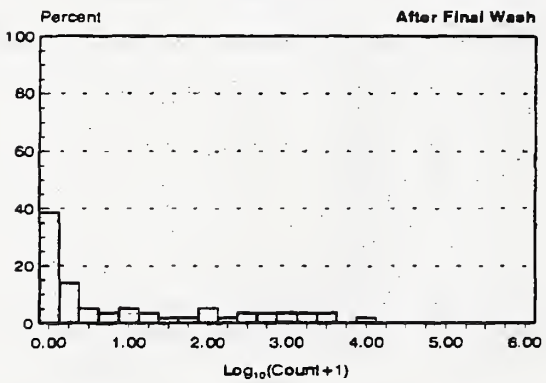


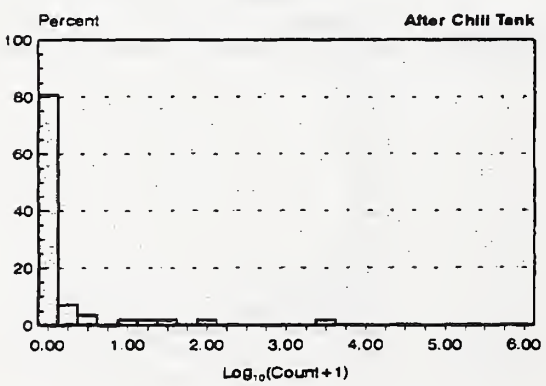
Figure 22. *S. aureus* Distributions - Plant PS1

Phase 1

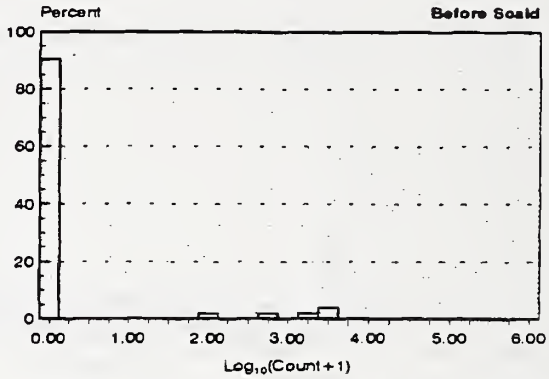


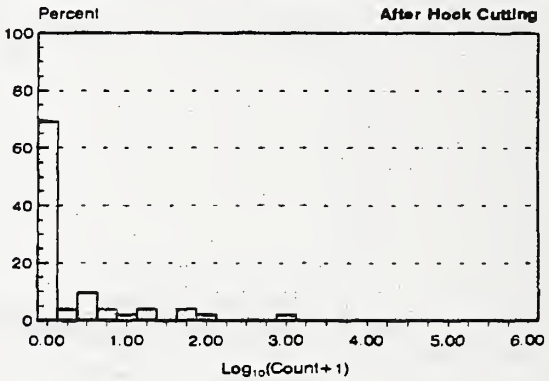


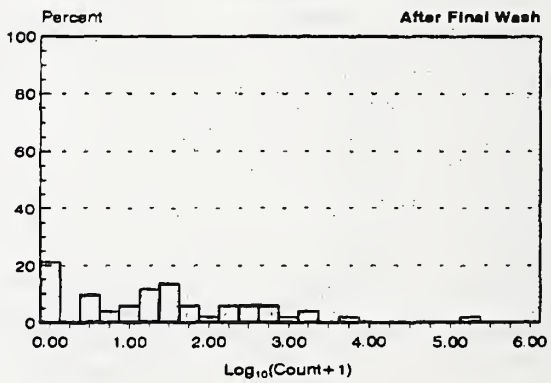




Phase 3







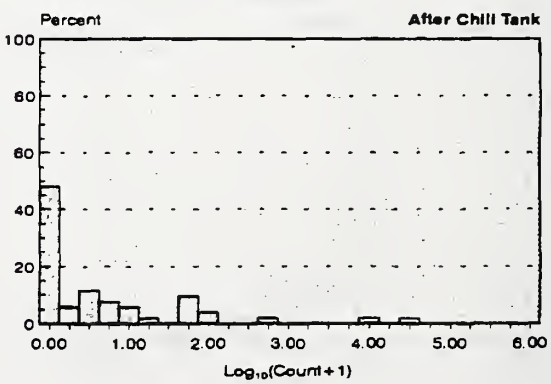
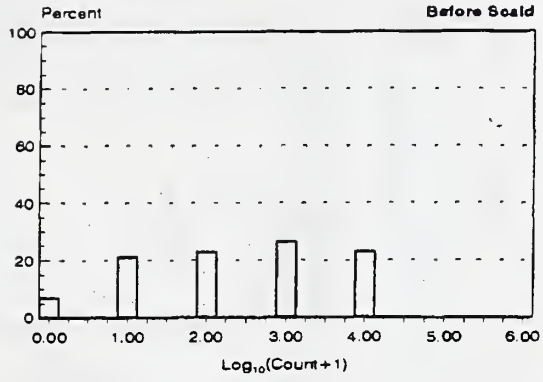
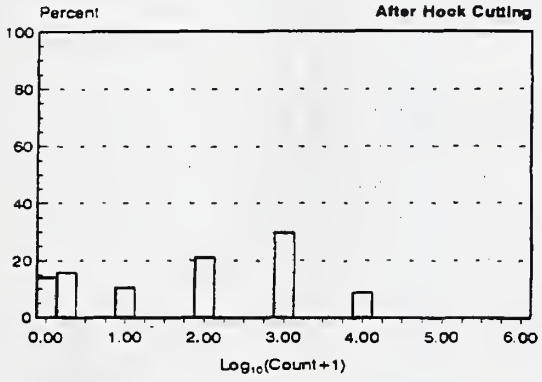
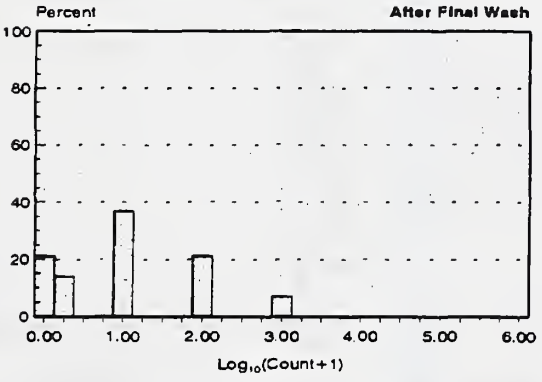


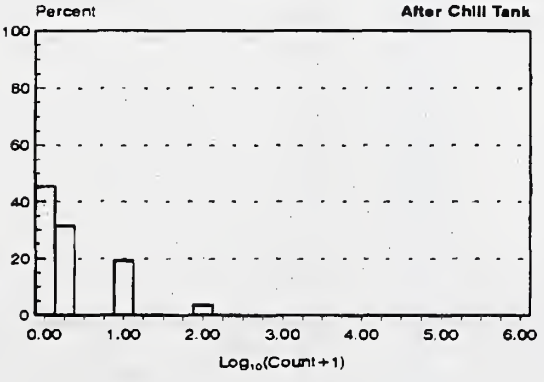
Figure 23. GFA Distributions - Plant PS1

Phase 1

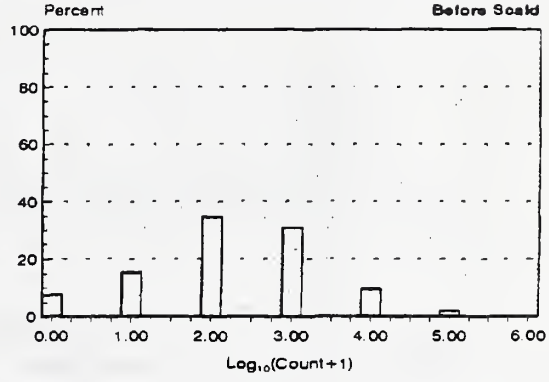


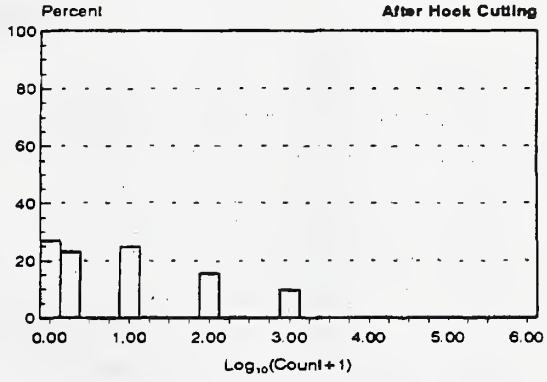


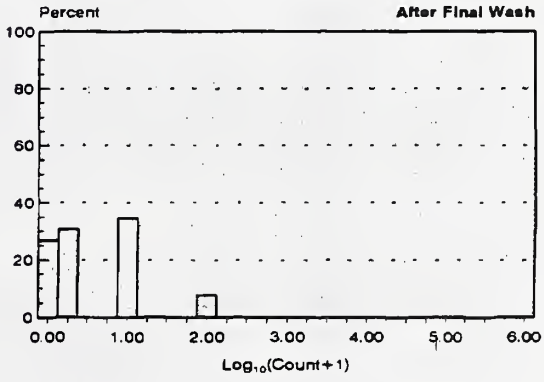




Phase 3







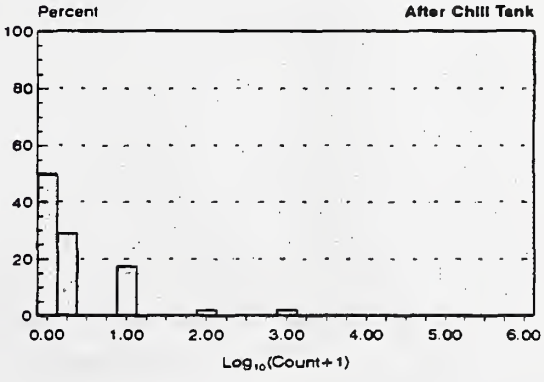
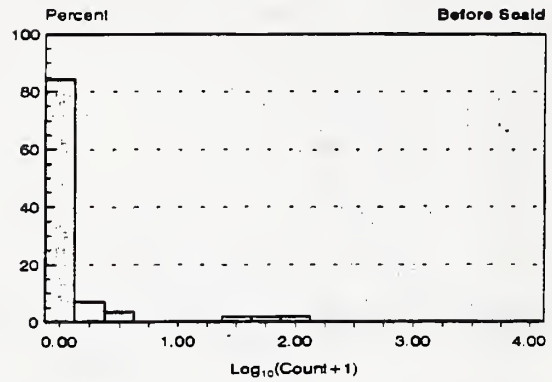
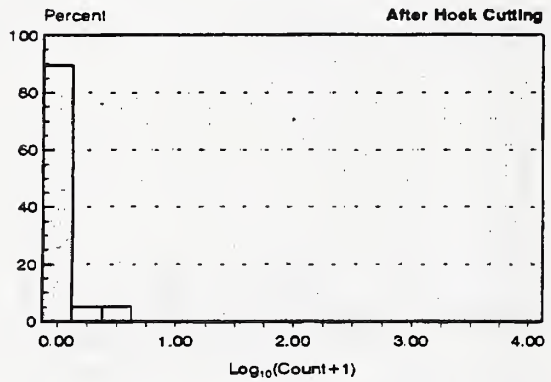
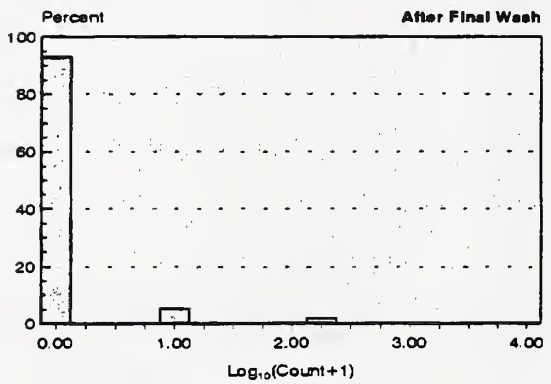


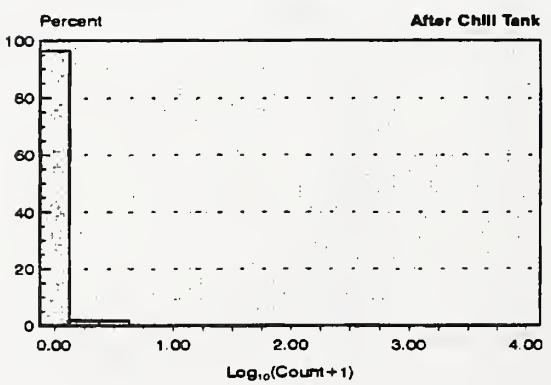
Figure 24. *Salmonella* Distributions - Plant PS1

Phase 1

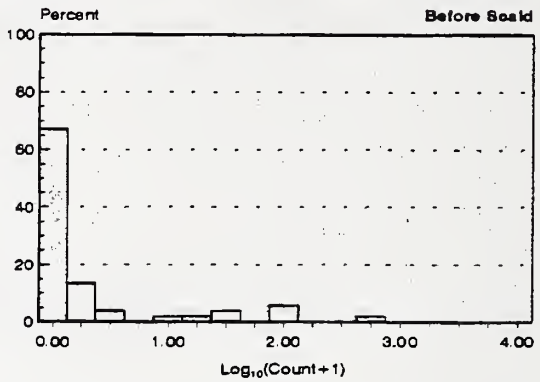


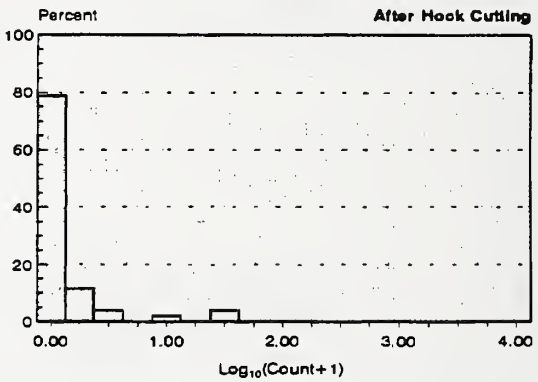


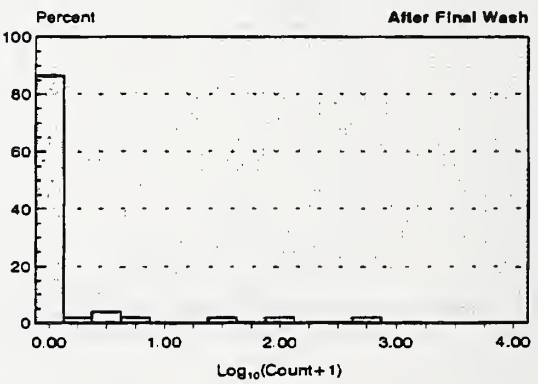




Phase 3







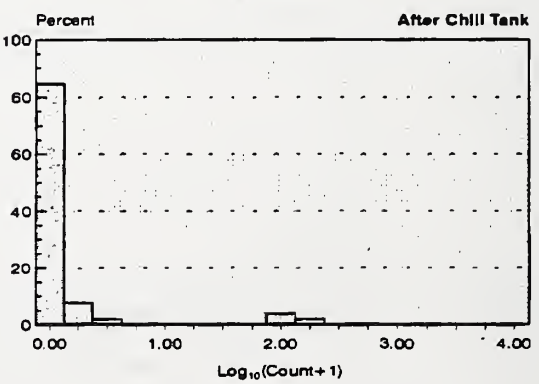
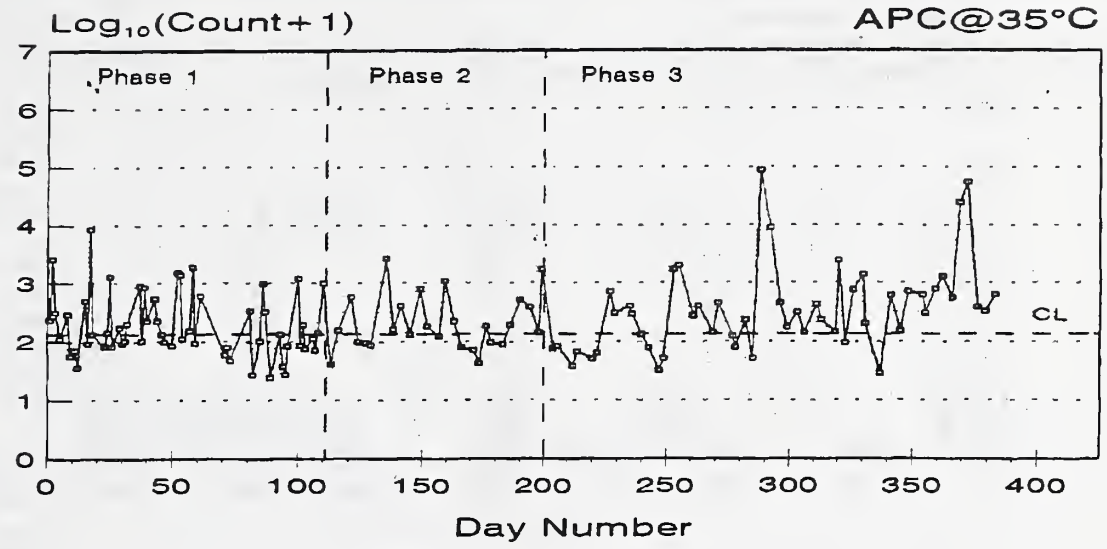
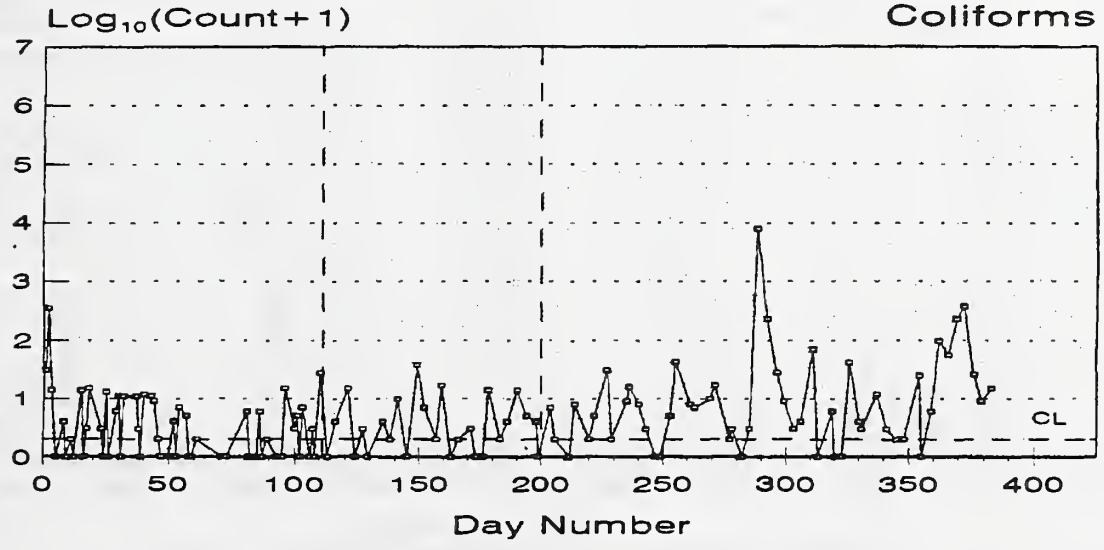
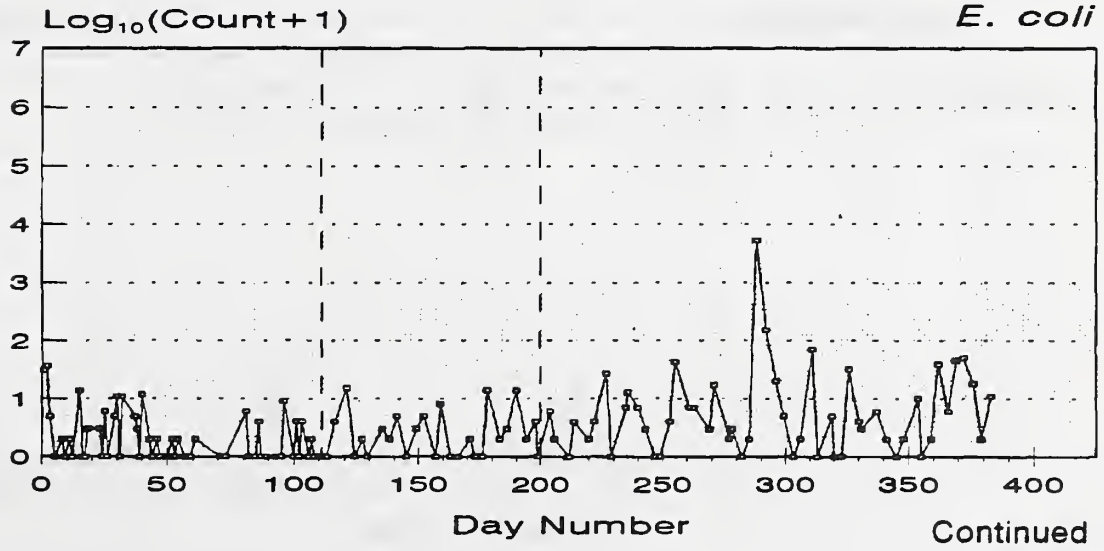


Figure 25. Run Charts for Microbiology Data
Poultry Slaughter Plant 1 - After Chill Tank

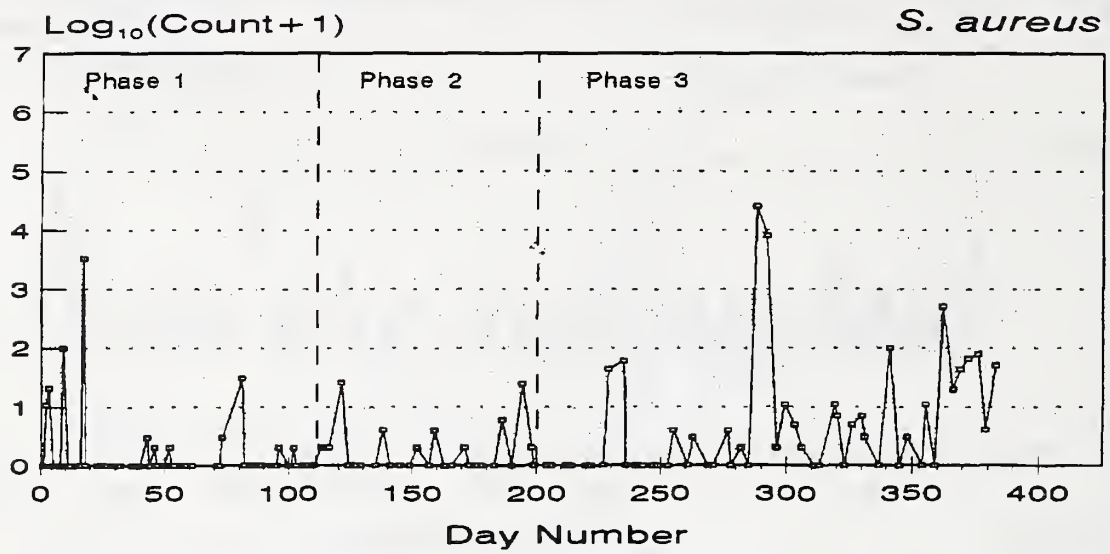


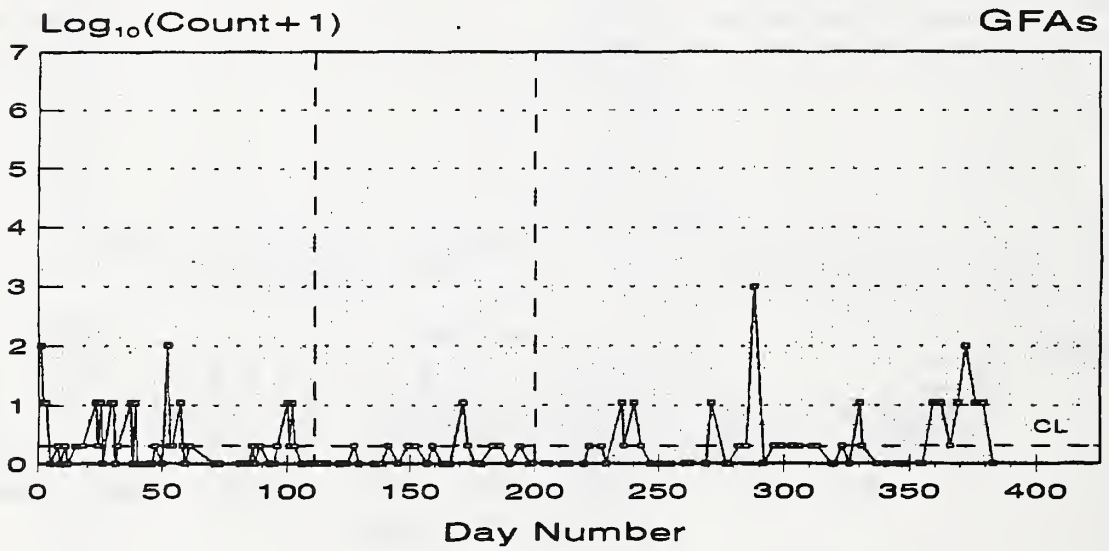




Continued

Figure 25 (continued). Run Charts for Microbiology Data
Poultry Slaughter Plant 1 - After Chill Tank





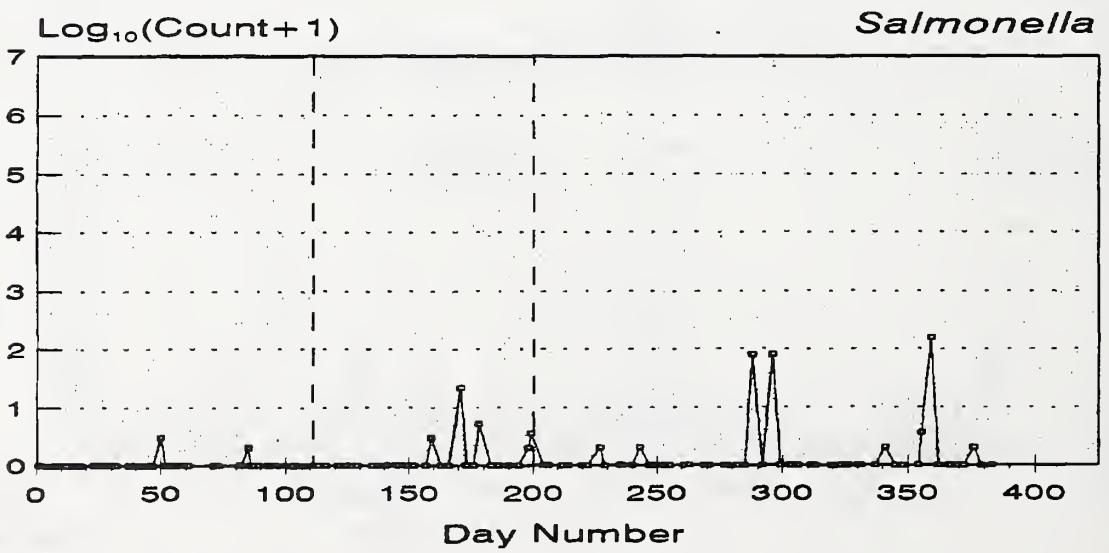


TABLE 41: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III POULTRY SLAUGHTER PLANT 2

Process Step	APC @ 35°C	Coliforms	*E. coli*	*S. aureus*	GFAs	Salmonella
Receiving*						
Hanging						
Stunning						
Killing						
Bleeding	1,590,000	2,770	1,430	8	588	18
| —	4,790,000	3,590	2,180	22	197	2
Scalding*						
Picking						
Singeing						
Remove Head						
Washing						
Hock cutter						
| —	8,980	158	58	2	38	1
Transf/rehang	11,200	246	119	22	4	1
Oil Sac cut						
Vent/etc.*						
Presenting						
Inspection						
Helper						
Liver/Heart						
Gut cutter						
Gizzard						
Cropping						
Break Neck						
Remove Lung						
Trimmer						
House Check						
Final Wash*						
| —	902	5	3	1	5	1
Neck cutter	1,900	18	8	6	2	1
Carcass chill*						
| —	832	9	3	1	4	2
Sort/etc.	1,180	18	7	3	2	1
Package/etc.						
Storage/Dist*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. *Salmonella* was reported on a per bird basis; other values were reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=1) were assigned a value of 1 in computing the geometric mean.

Table 42 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III.

Figures 26 through 31 show the distribution for APC @ 35°C, coliforms, *E. coli*, *S. aureus*, GFA, and *Salmonella*. The results generally show decreasing levels for all factors as the product moves through processing. Phase I and Phase III results are similar.

Run charts for the six quantitative microbiology factors are presented in Figure 32. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C , coliforms, *E. coli*, and GFAs.

Percent positive *Salmonella* was proposed to be used for process control verification; therefore, percent positives for Phases I and III were compared. The difference, 30.2 percent vs 9.8 percent, was found to be statistically significant ($P<.05$). Figure 31 and Table 42 show that *Salmonella* results for Phase III tended to be lower than those for Phase I. This difference was to be expected, since the *Salmonella* results for the incoming birds in Phase III were lower than those in Phase I. The median chlorine levels were 10 ppm in both Phase I and Phase III and has no explanatory value.

In summary, the HACCP microbiological assessment in Poultry Slaughter Plant PS 2 showed a reduction in *Salmonella*. The microbiological profile of the product produced during both phases was indicative of good manufacturing procedures.

Poultry Slaughter plant 3 (PS 3):

Table 43 shows geometric means for the six quantitative microbiology factors at the different sampling points in PS 3 during Phases I and III. It also relates the sampling points to the generic HACCP Poultry Slaughter model and demonstrates the change in microbial profile during the process. As seen in the table, the microbiological levels were high for incoming birds, but each successive step reduced the microbial population on the birds.

Table 44 gives more detailed summary statistics for the same factors at the three sampling points during Phases I and III.

Figures 33 through 38 show the distribution for APC @ 35°C, coliforms, *E. coli*, *S. aureus*, GFA, and *Salmonella*. The results generally show decreasing levels for all factors as the product moves through processing. Phase I and Phase III results are similar.

TABLE 42: SUMMARY STATISTICS FOR MICROBIAL FACTORS POULTRY SLAUGHTER PLANT 2

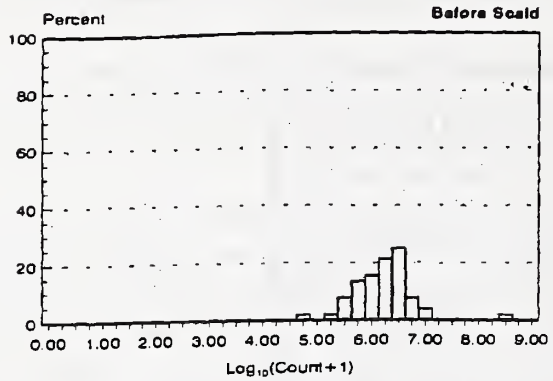
Microbial Factor	Phase	Num	Before Scald *			After Hock Cut			After Final Wash			After Chill Tank		
			Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std
APC @35°C	1	53	100.0	6.2	.55	100.0	4.0	.74	100.0	3.0	.48	100.0	2.9	.60
	3	51	100.0	6.7	.59	100.0	4.0	.80	100.0	3.3	.75	100.0	3.1	.92
Coliforms	1	53	100.0	3.4	.59	100.0	2.2	1.16	79.2	.8	.77	92.5	1.0	.61
	3	51	100.0	4.0	.82	98.0	2.4	1.17	98.0	1.0	.98	96.1	1.3	.89
E. coli	1	53	98.1	3.2	.58	90.6	1.9	1.11	54.7	.8	.77	69.8	.7	.45
	3	51	100.0	3.3	.90	98.0	2.1	1.27	88.2	1.0	.98	84.3	1.0	.98
S. aureus	1	53	26.9	3.4	.96	32.1	.9	1.00	17.0	.8	.53	9.4	.9	.81
	3	51	33.3	4.0	.89	84.3	1.6	.72	76.5	1.0	.62	58.8	.9	.67
GFAs	1	53	98.1	2.8	1.14	88.7	1.8	1.02	81.1	.9	.91	77.4	.9	.64
	3	51	96.1	2.4	.98	70.6	.8	.98	58.8	.6	.72	41.2	.9	.60
Salmonella	1	53	84.9	1.8	.96	3.8	.7	.55	15.1	.8	.96	30.2	.8	.64
	3	51	27.5	.8	.89	7.8	.9	.77	2.0	.4		9.8	.6	.60

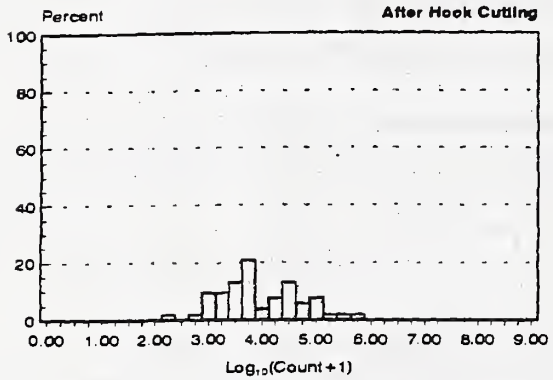
* 52 Samples before scald

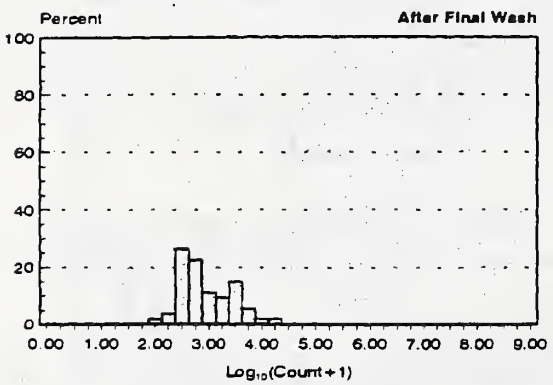
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

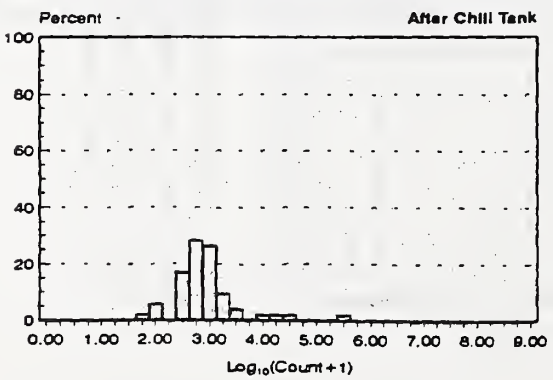
Figure 26. APC@35°C Distributions - Plant PS2

Phase 1

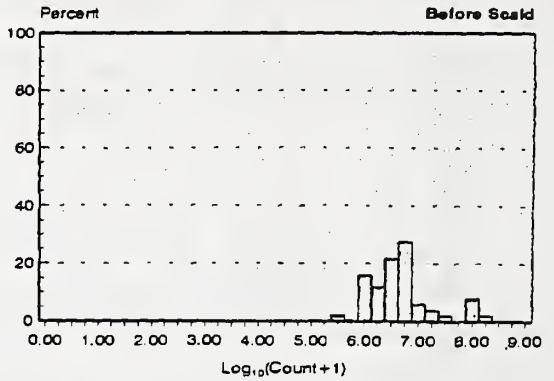


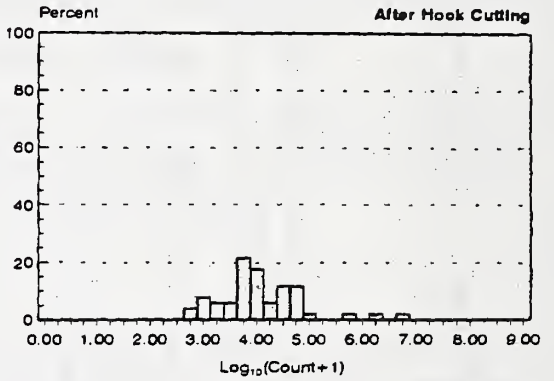


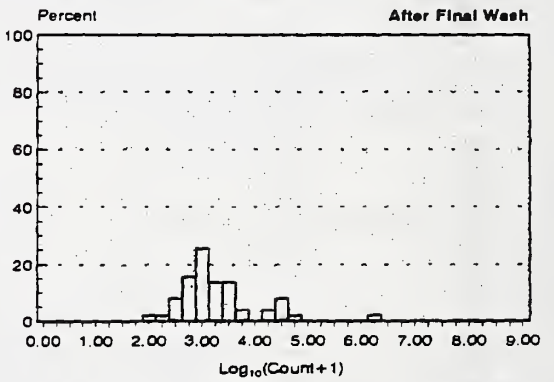




Phase 3







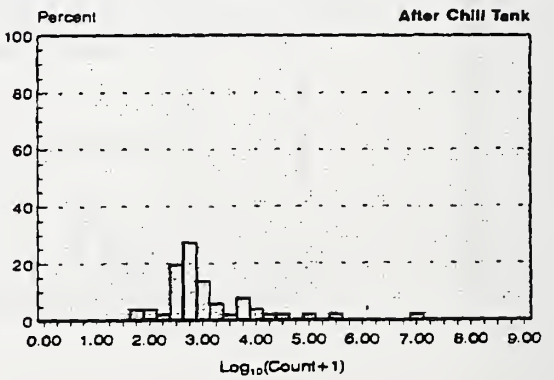
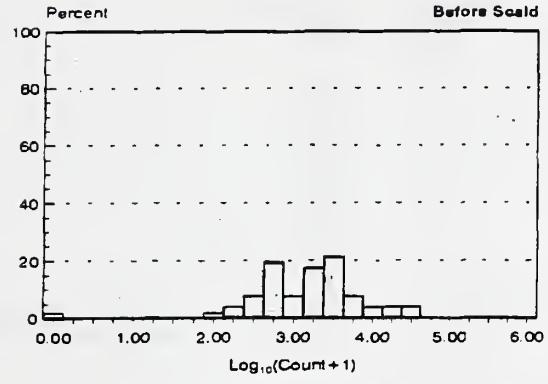
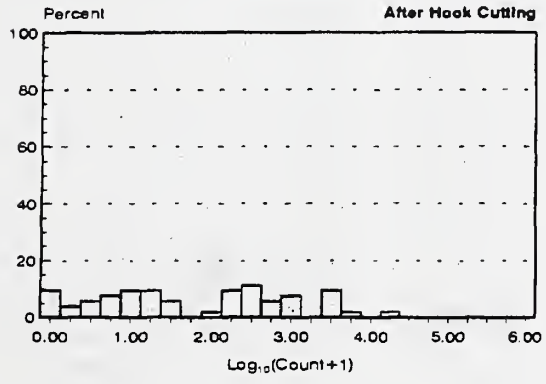
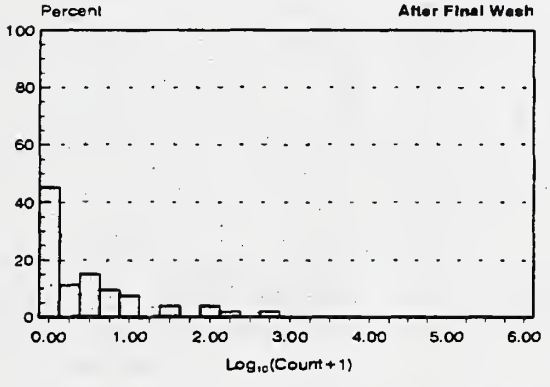


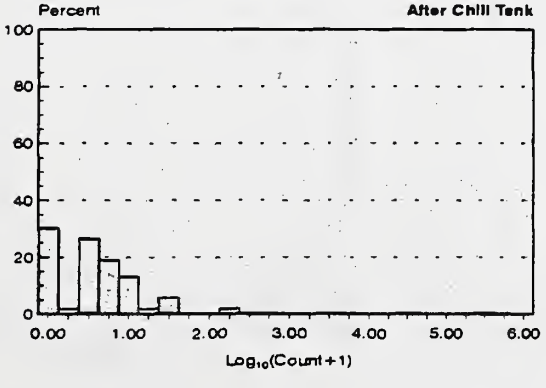
Figure 28. *E. coli* Distributions - Plant PS2

Phase 1

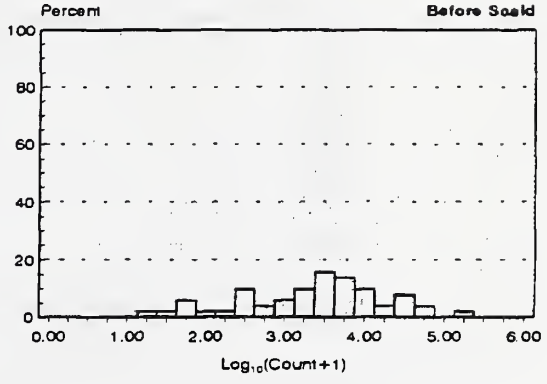


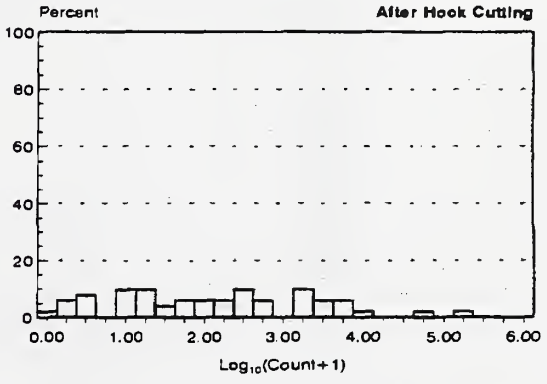


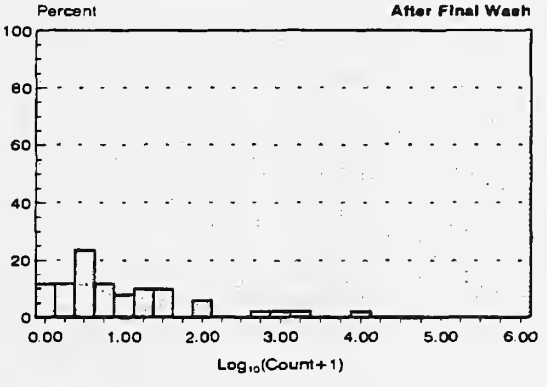




Phase 3







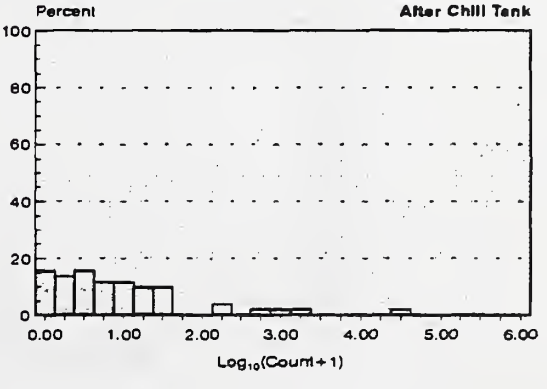
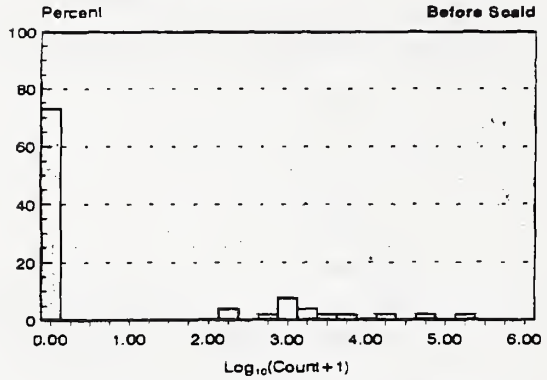
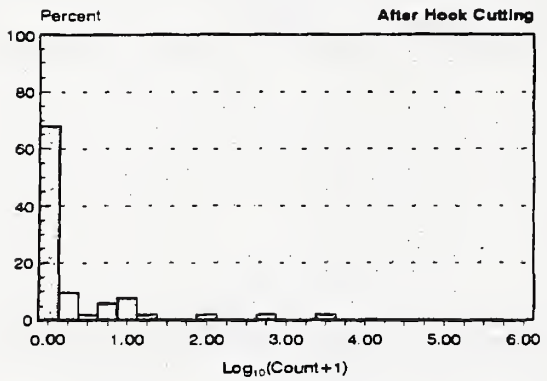
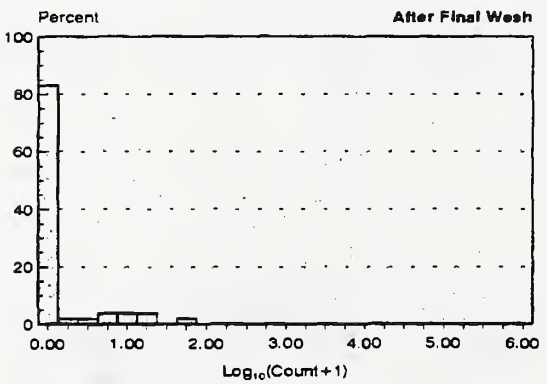


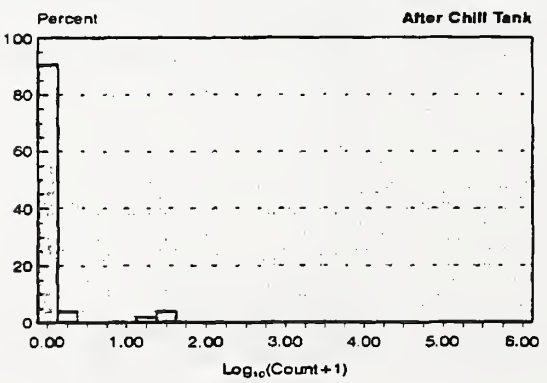
Figure 29. *S. aureus* Distributions - Plant PS2

Phase 1

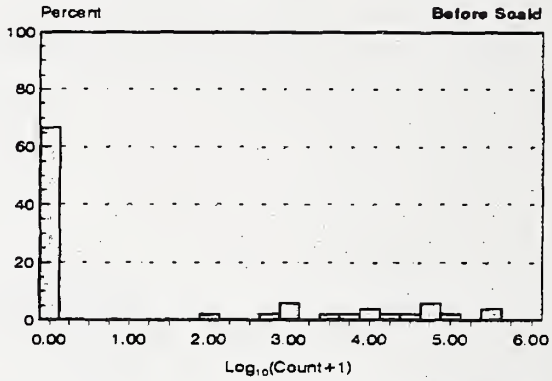


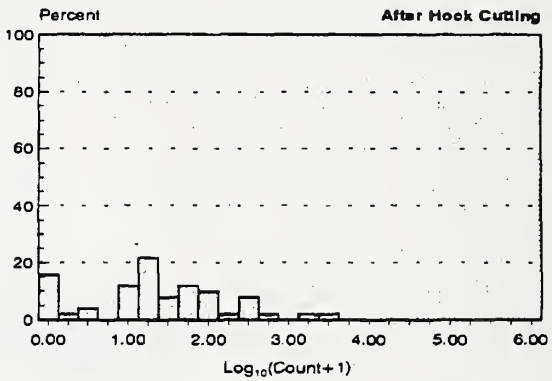


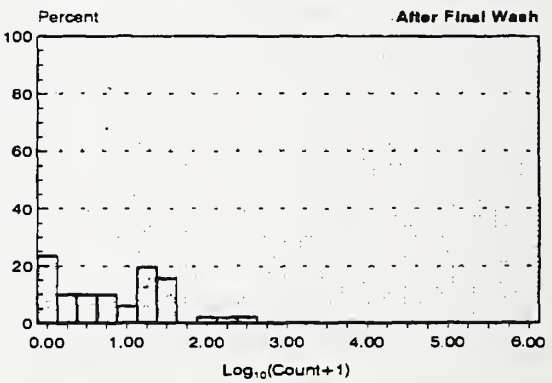




Phase 3







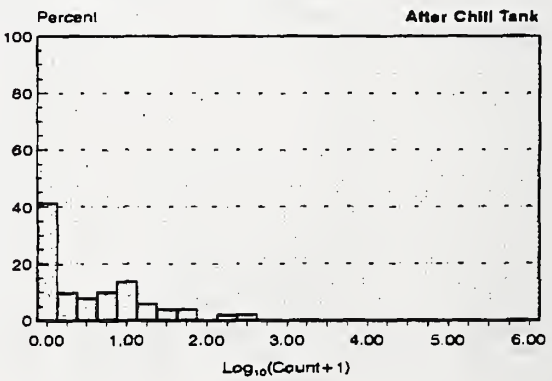
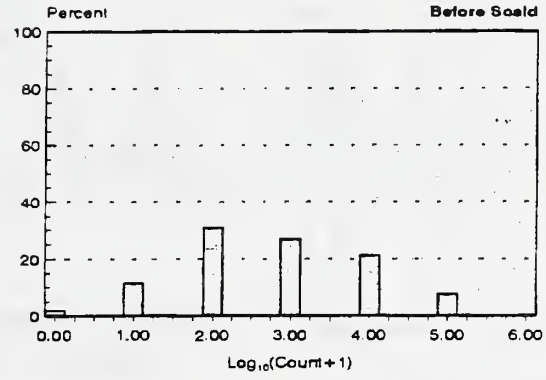
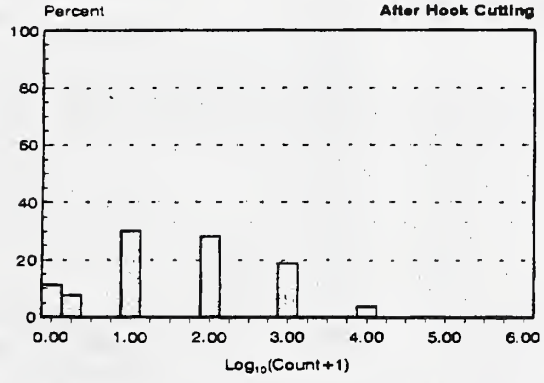
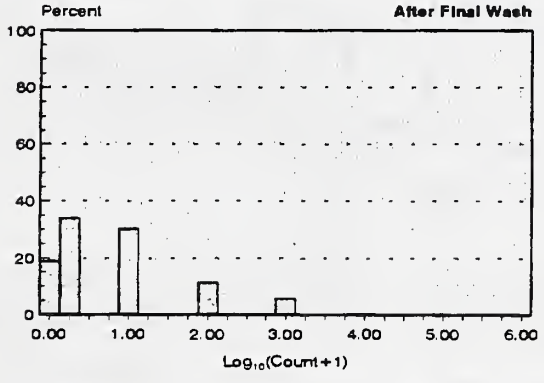


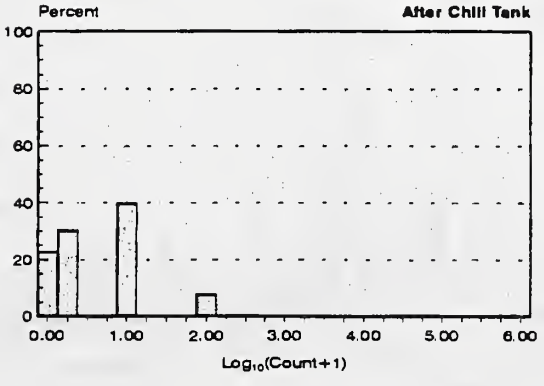
Figure 30. GFA Distributions - Plant PS2

Phase 1

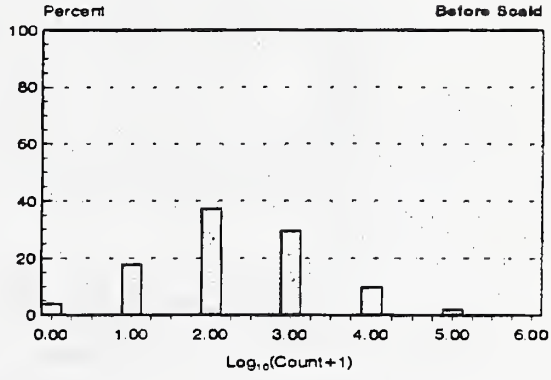


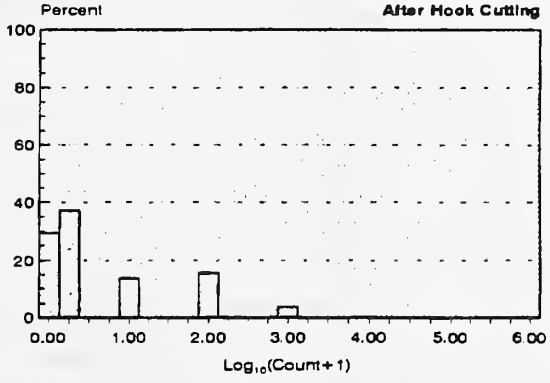


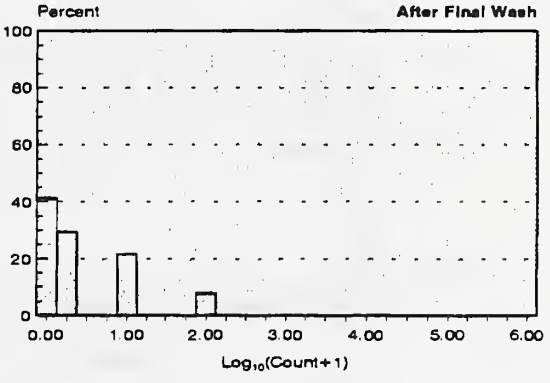




Phase 3







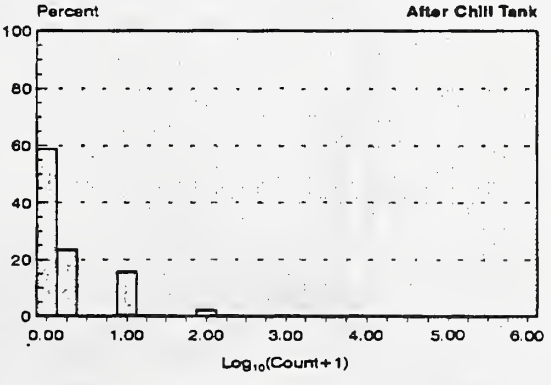
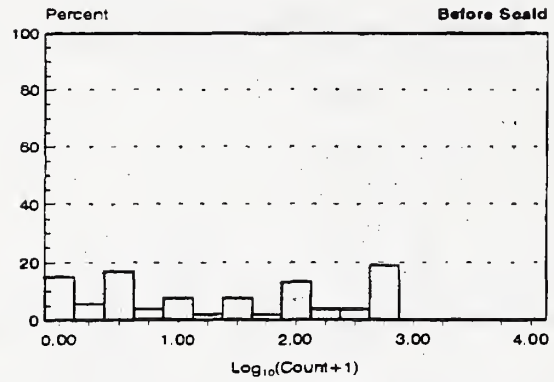
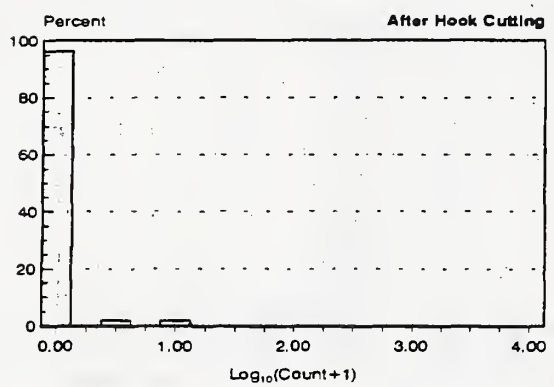
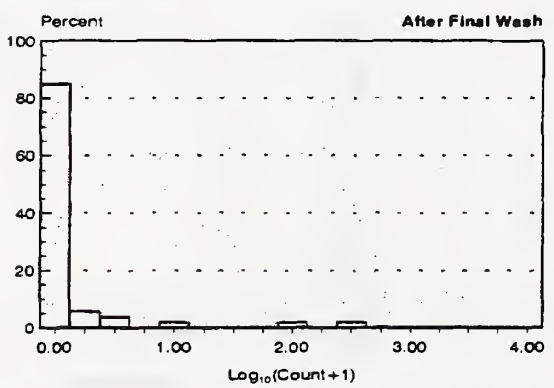


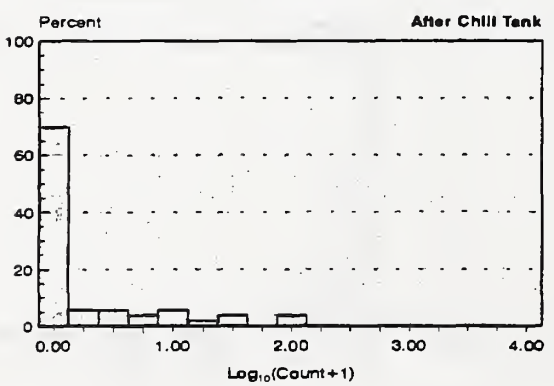
Figure 31. *Salmonella* Distributions - Plant PS2

Phase 1

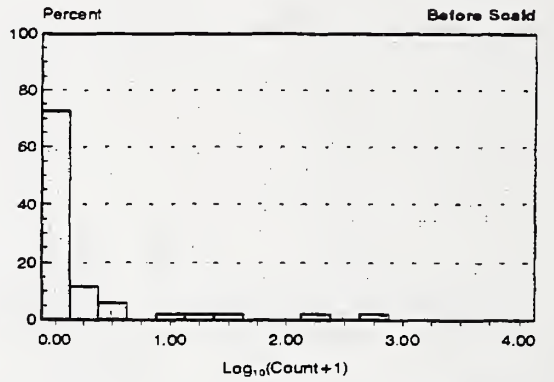


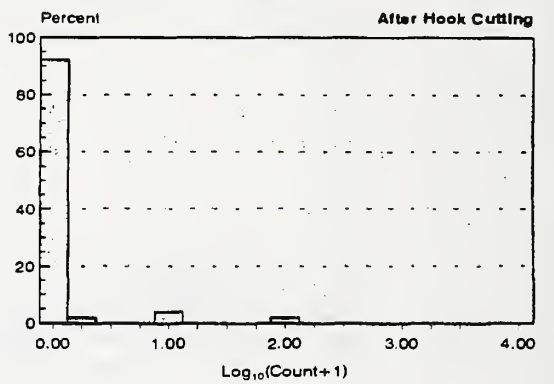


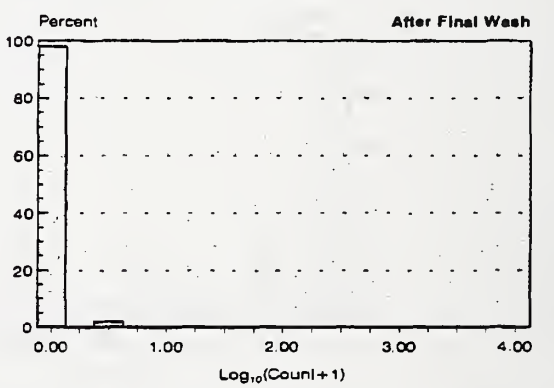




Phase 3







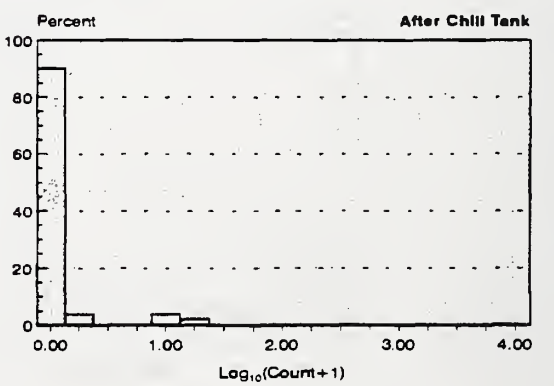
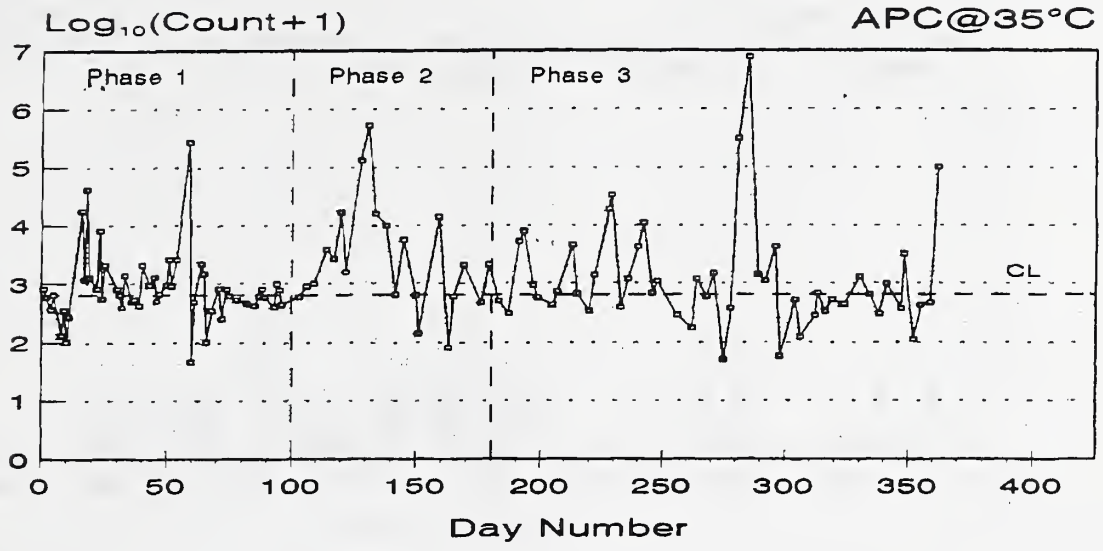
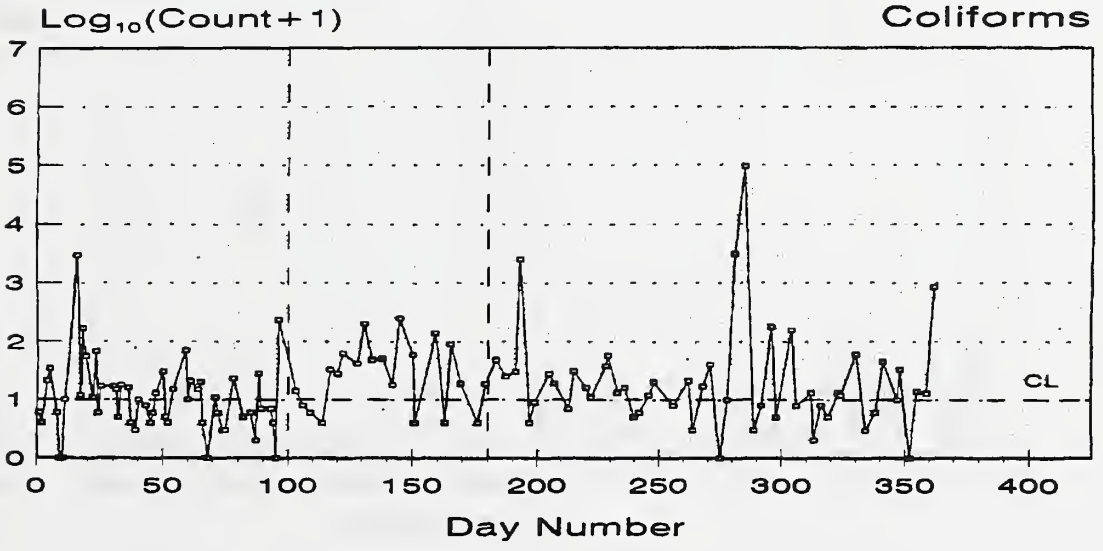
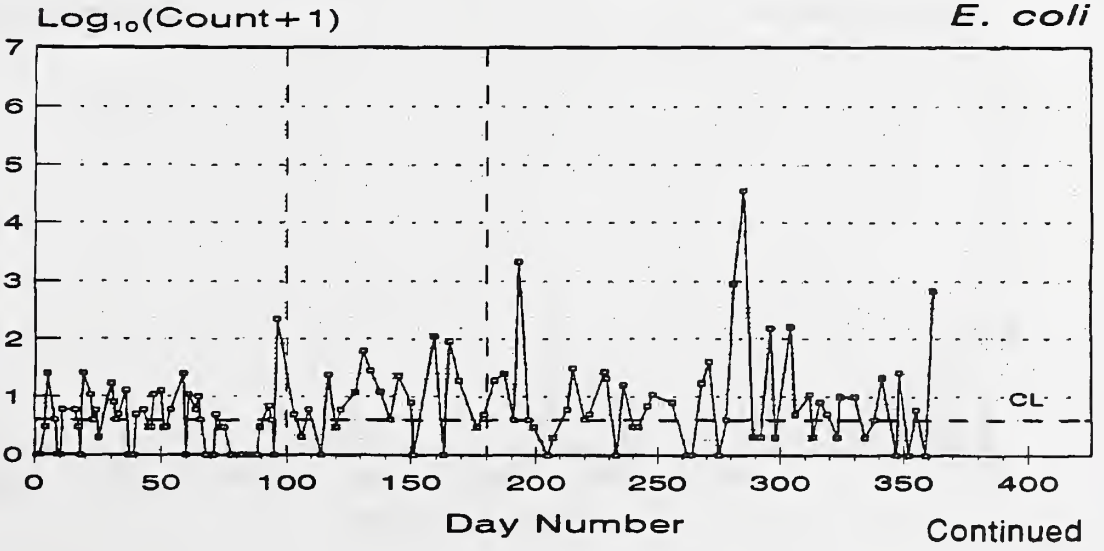


Figure 32. Run Charts for Microbiology Data
Poultry Slaughter Plant 2 - After Chill Tank

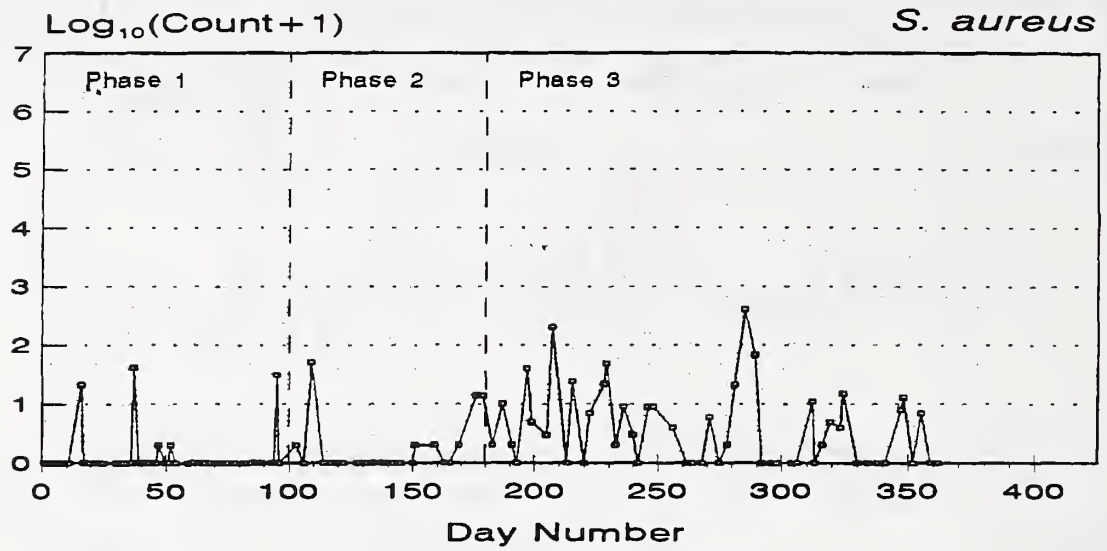


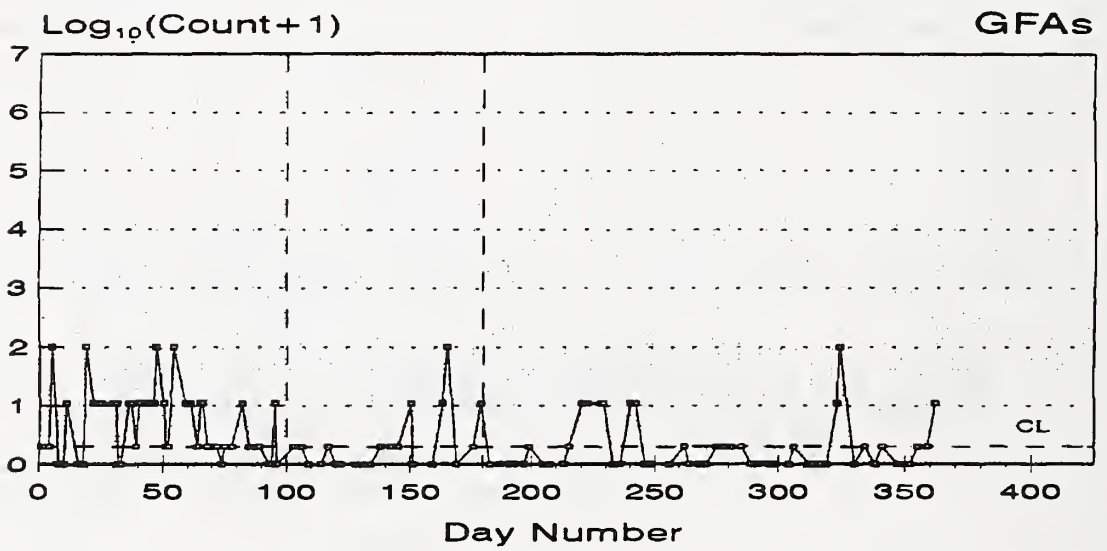




Continued

Figure 32 (continued). Run Charts for Microbiology Data
Poultry Slaughter Plant 2 - After Chill Tank





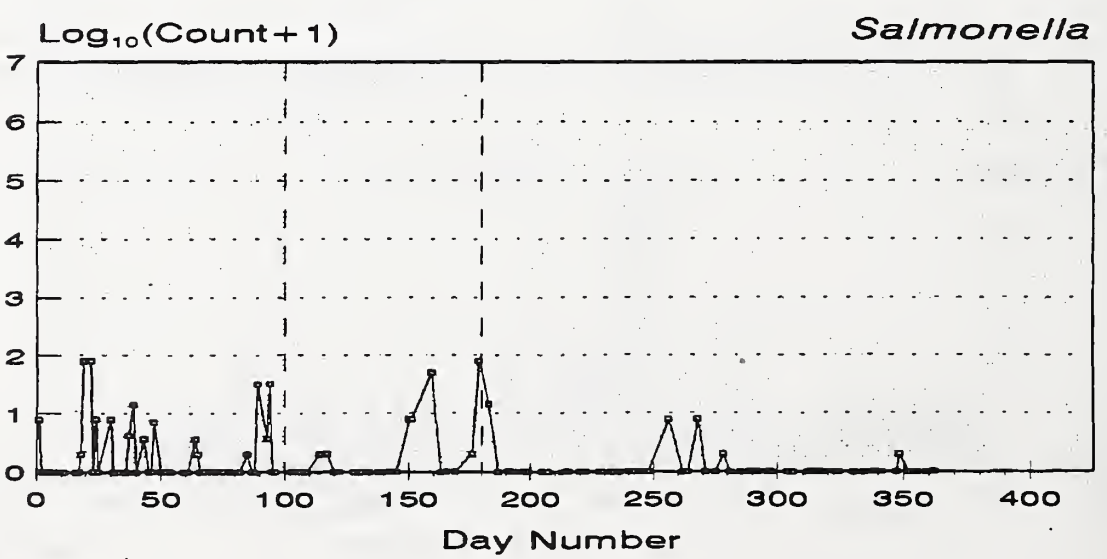


TABLE 43: MICROBIAL PROFILE AT DIFFERENT PROCESS STEPS GEOMETRIC MEAN - PHASE I/PHASE III POULTRY SLAUGHTER PLANT 3

Process Step	APC @ 35°C	Coliforms	*E. coli*	*S. aureus*	GFAs	Salmonella
Receiving*						
Hanging						
Stunning						
Killing						
Bleeding	2,440,000	450	124	5	248	6
| —	3,470,000	868	324	9	794	1
Scalding*						
Picking						
Singeing						
Remove Head						
Washing						
Hock cutter						
| —	10,900	44	20	18	16	2
Transf/rehang	8,000	66	37	9	6	1
Oil Sac cut						
Vent/etc.*						
Presenting						
Inspection						
Helper						
Liver/Heart						
Gut cutter						
Gizzard						
Cropping						
Break Neck						
Remove Lung						
Trimmer						
House Check						
Final Wash*						
| —	1,140	5	2	8	3	1
Neck cutter	1,620	9	5	21	2	1
Carcass chill*						
| —	231	3	2	2	2	1
Sort/etc.	439	6	3	4	1	1
Package/etc.						
Storage/Dist*						

Notes:

1. * denotes microbiological Critical Control Point (CCP)
2. *Salmonella* was reported on a per bird basis; other values were reported on a per gram basis.
3. Results below the Minimum Detectable Level (MDL=1) were assigned a value of 1 in computing the geometric mean.

TABLE 44: SUMMARY STATISTICS FOR MICROBIAL FACTORS POULTRY SLAUGHTER PLANT 3

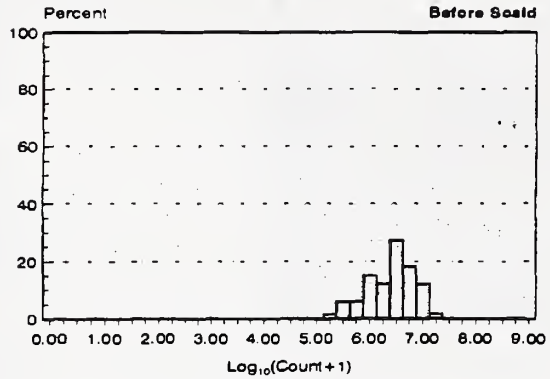
Microbial Factor	Phase	Num	Before Scald			After Hock Cut			After Final Wash			After Chill Tank		
			Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std	Pct	Ave	Std
APC @35°C	1	*66	100.0	6.4	.46	100.0	4.0	.77	100.0	3.1	.59	100.0	2.4	.69
	3	50	100.0	6.5	.58	100.0	3.9	.71	100.0	3.2	.74	100.0	2.6	.87
Coliforms	1	*66	98.5	2.7	.67	97.0	1.7	.89	86.2	.8	.66	65.2	.7	.72
	3	50	100.0	2.9	1.00	100.0	1.8	1.23	84.0	1.1	.98	86.0	.9	.99
E. coli	1	*66	90.9	2.3	.81	92.4	1.4	.90	67.7	.5	.59	43.9	.6	.81
	3	50	88.0	2.9	1.01	92.0	1.7	1.29	66.0	1.1	.98	58.0	.9	1.00
S. aureus	1	*66	19.7	3.6	.50	72.7	1.7	.68	67.7	1.4	.67	31.8	.8	.60
	3	50	26.0	3.6	.69	72.0	1.3	.77	80.0	1.6	1.17	54.0	1.0	.89
GFAs	1	*66	100.0	2.4	.91	84.8	1.4	1.06	75.4	.6	.61	60.6	.5	.82
	3	50	100.0	2.9	.89	72.0	1.1	1.15	64.0	.6	.72	52.0	.3	.55
Salmonella	1	66	60.6	1.3	.99	27.3	1.0	.91	9.1	.5	.73	18.2	.7	.47
	3	50	12.0	.6	.44	4.0	1.7	.29	4.0	.2	.22	2.0	.8	

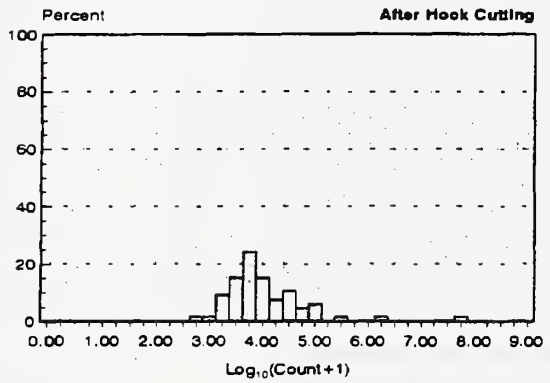
* 65 Samples after final wash

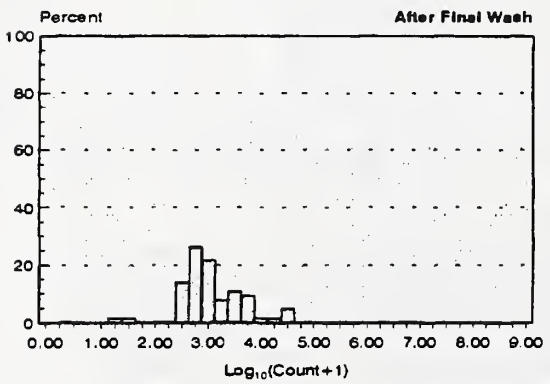
Num = Number of samples analyzed
Pct = Percent of samples positive
Ave = Average of $\log_{10}$ of positives
Std = Standard deviation of $\log_{10}$ of positives

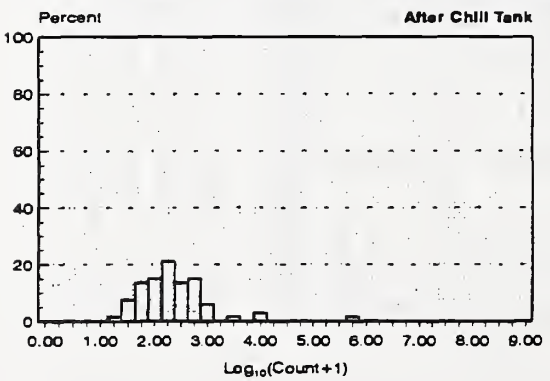
Figure 33. APC@35°C Distributions - Plant PS3

Phase 1

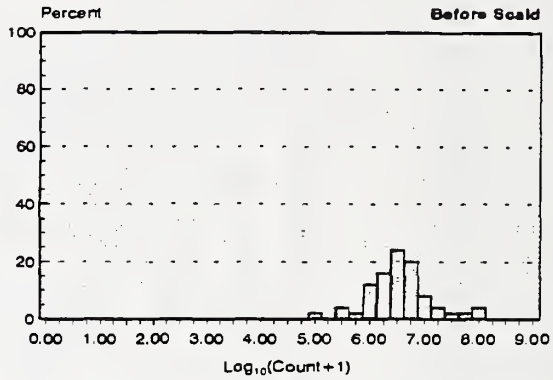


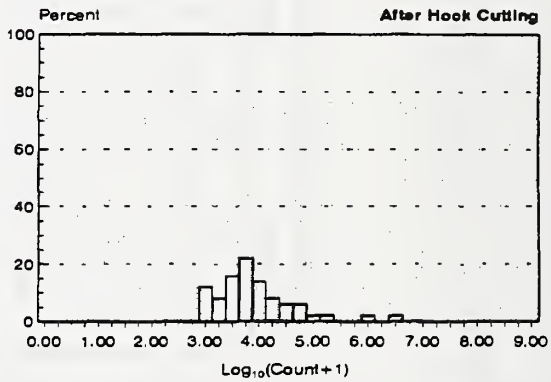


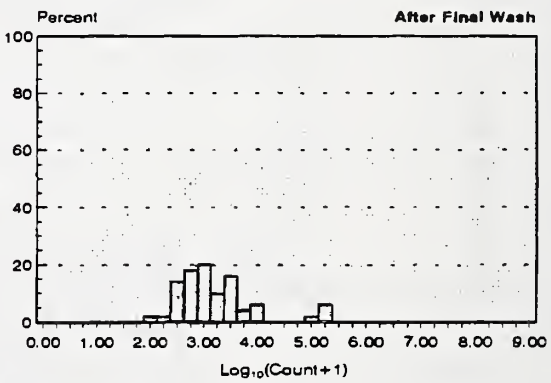




Phase 3







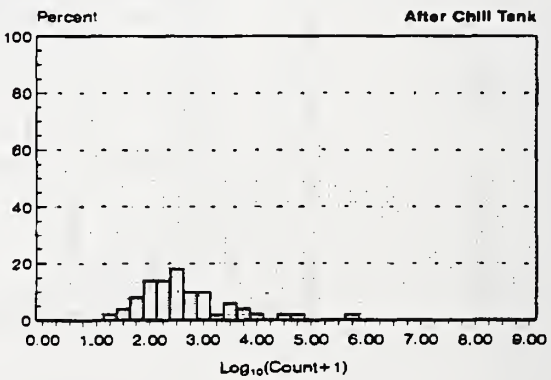
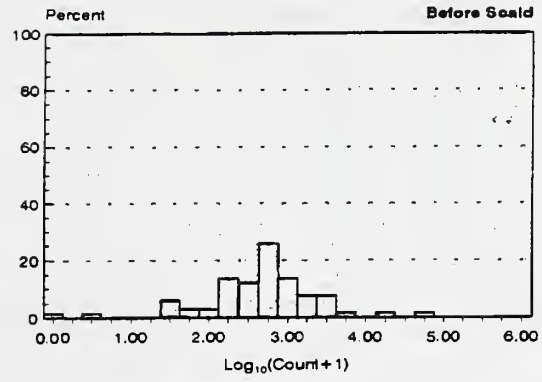
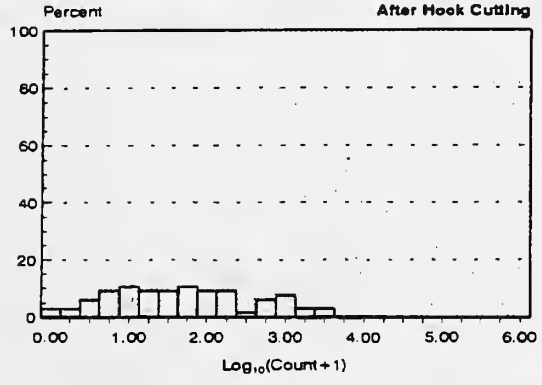
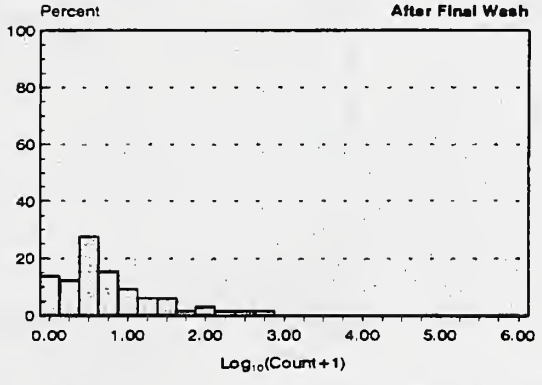


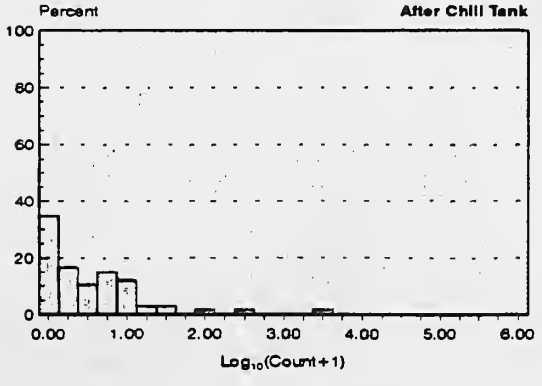
Figure 34. Coliform Distributions - Plant PS3

Phase 1

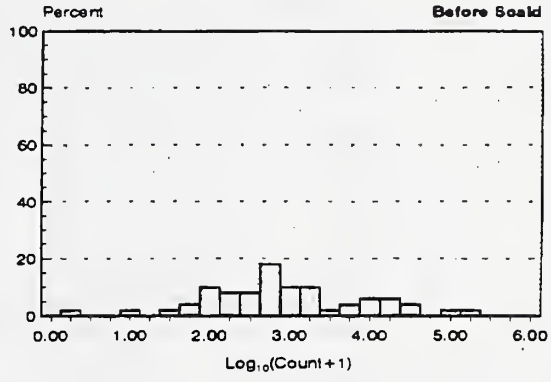


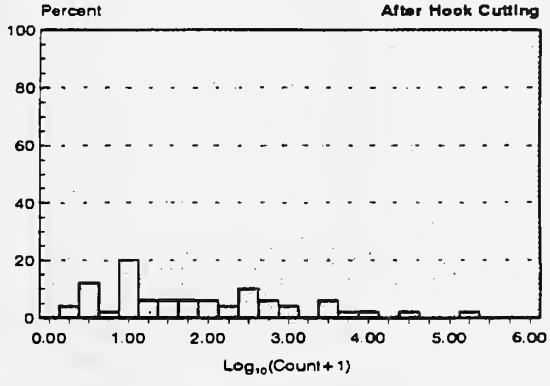


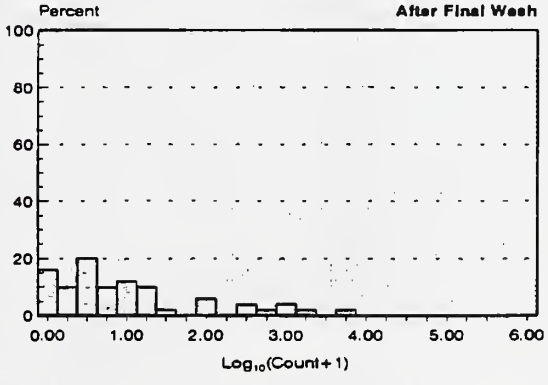




Phase 3







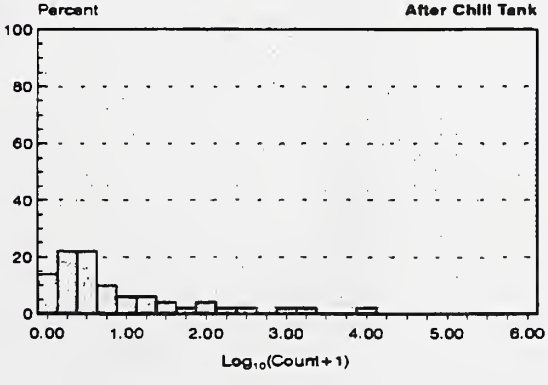
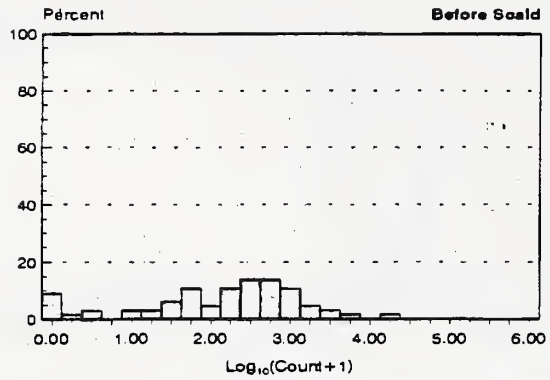
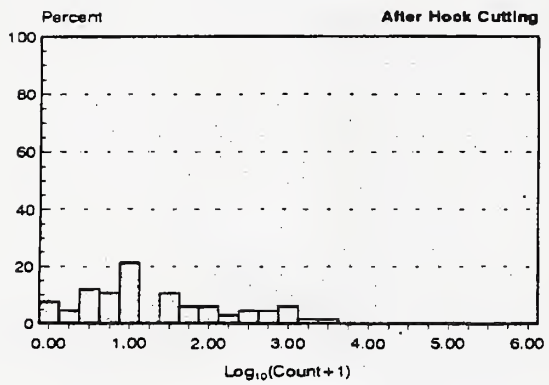
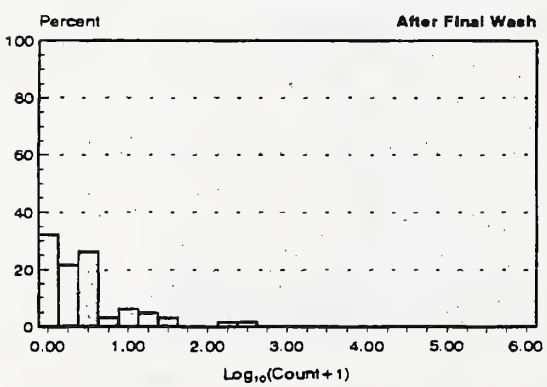


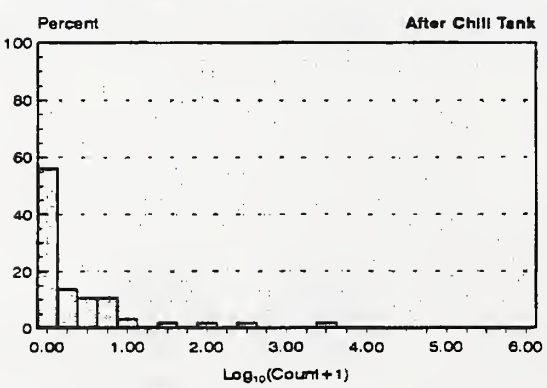
Figure 35. *E. coli* Distributions - Plant PS3

Phase 1

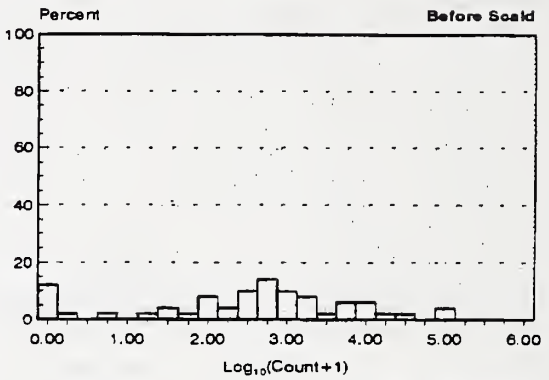


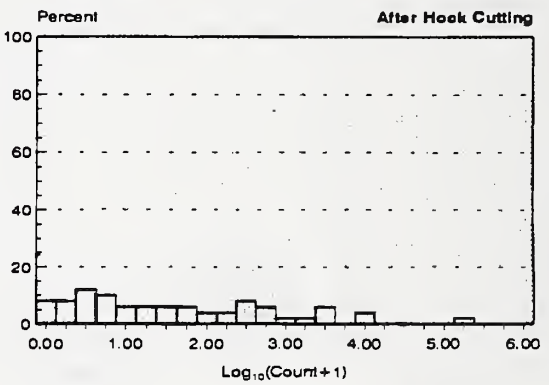


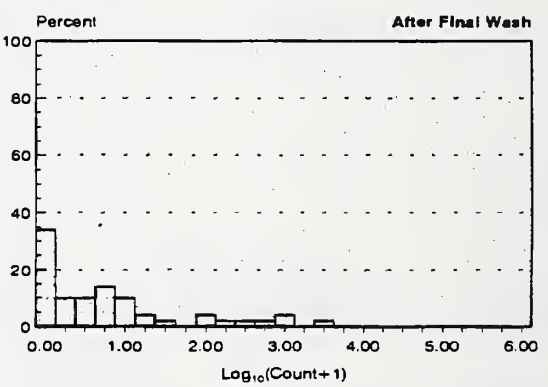




Phase 3







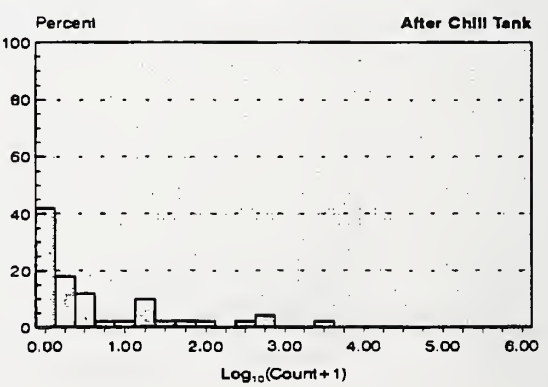
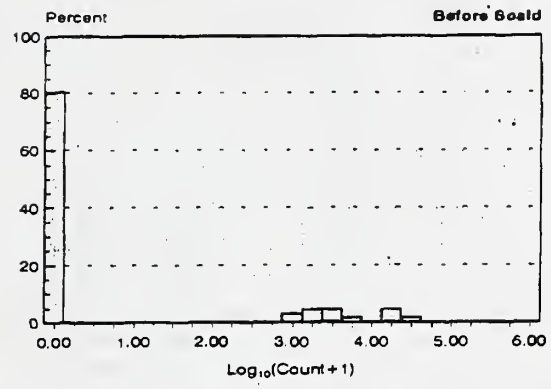
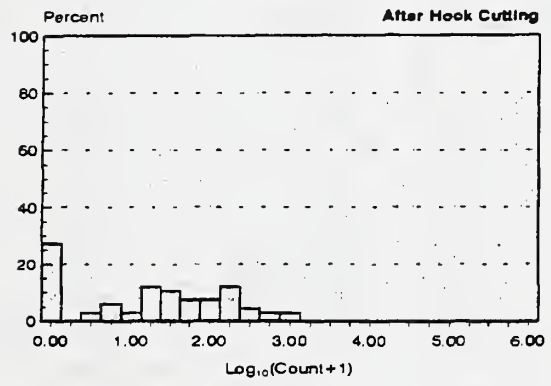
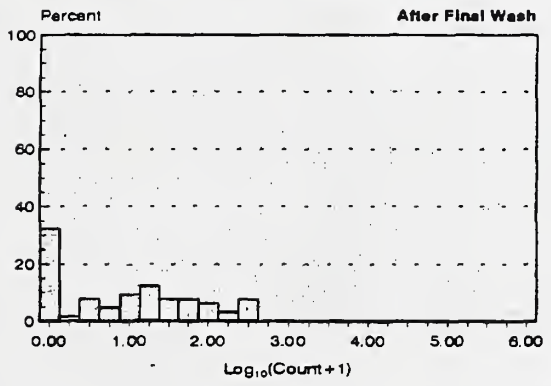


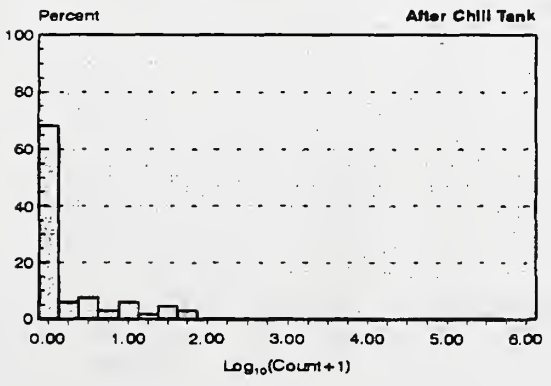
Figure 36. *S. aureus* Distributions - Plant PS3

Phase 1

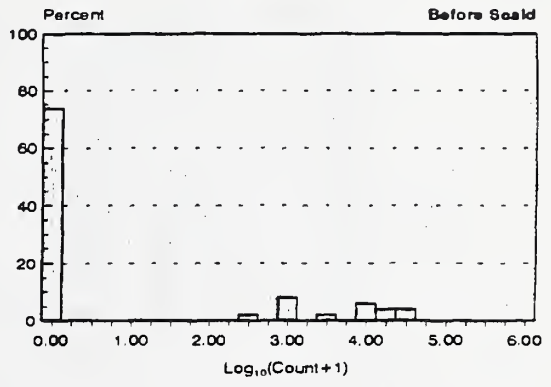


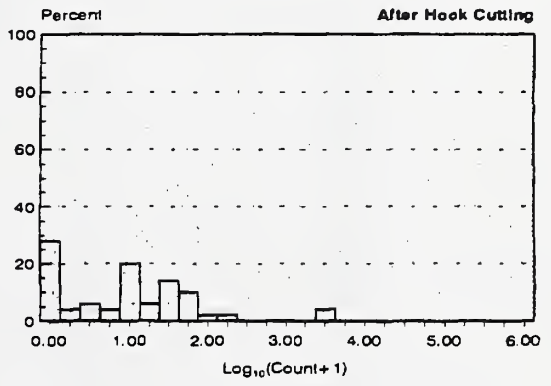


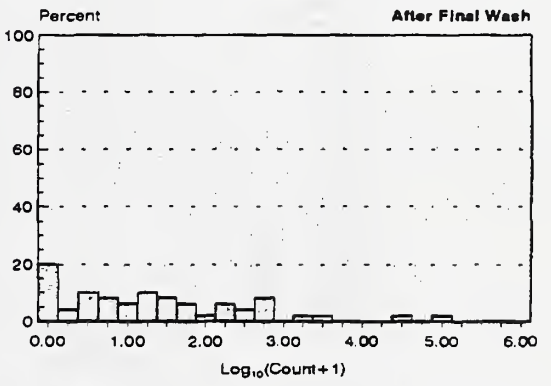




Phase 3







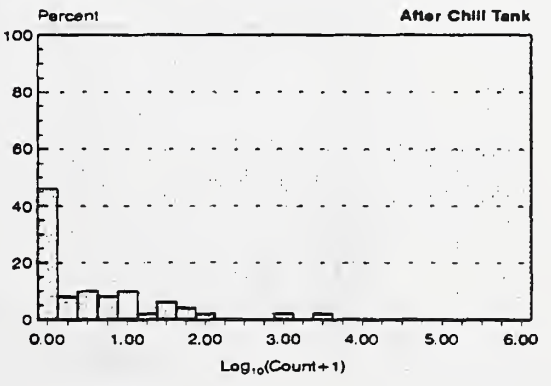
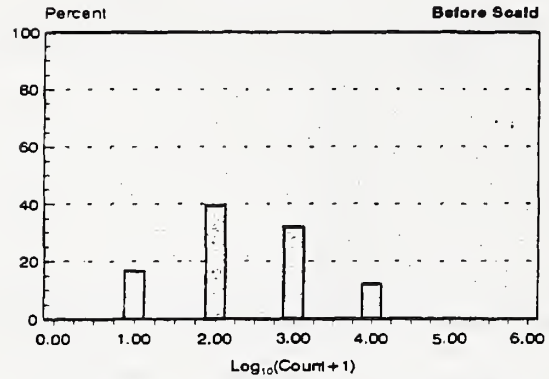
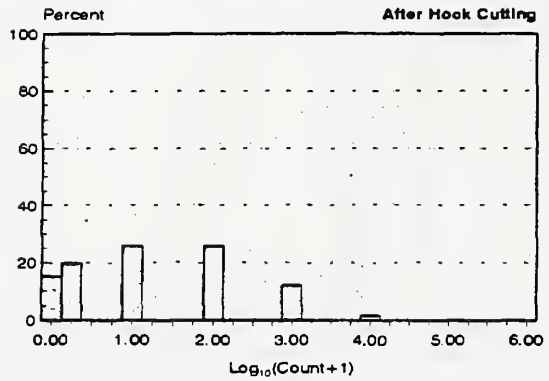
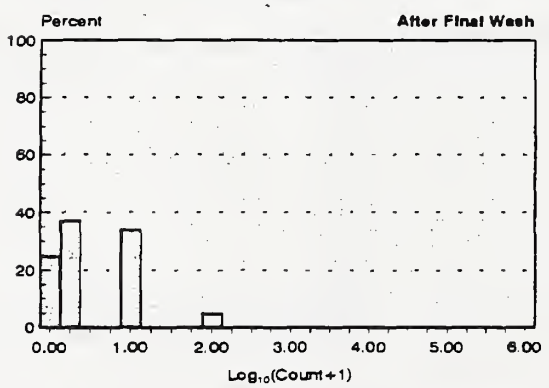


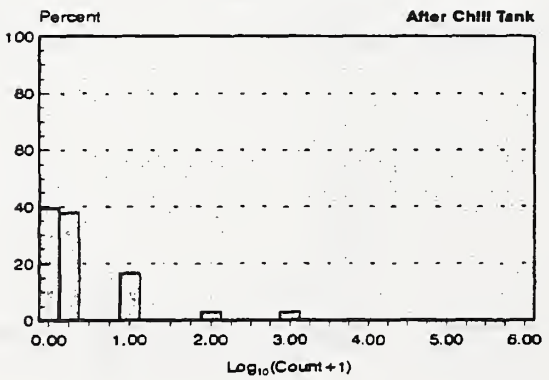
Figure 37. GFA Distributions - Plant PS3

Phase 1

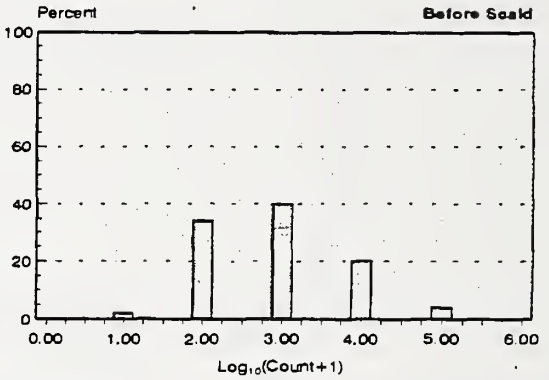


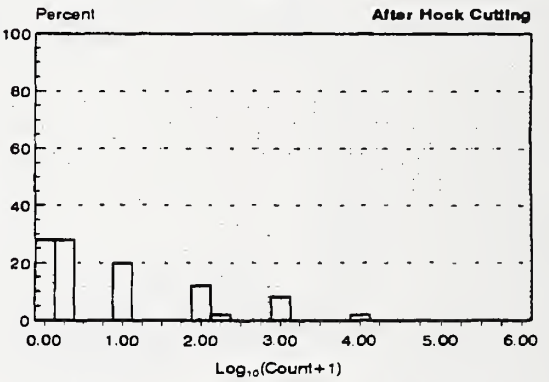


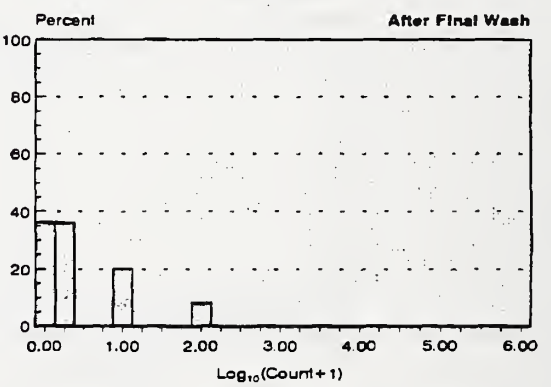




Phase 3







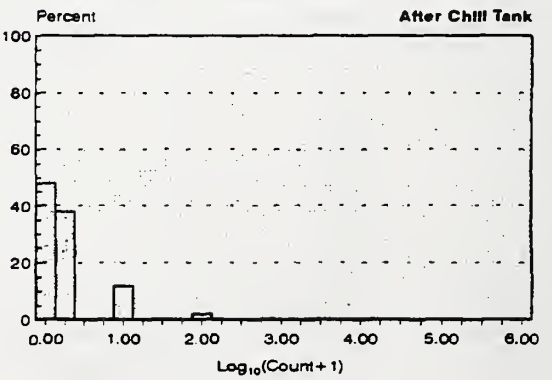
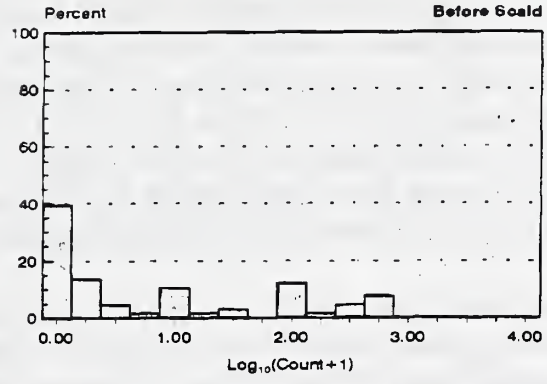
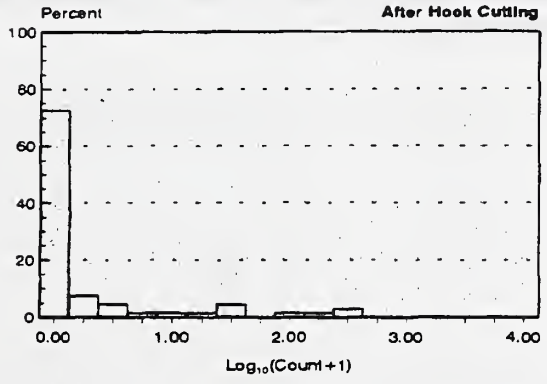
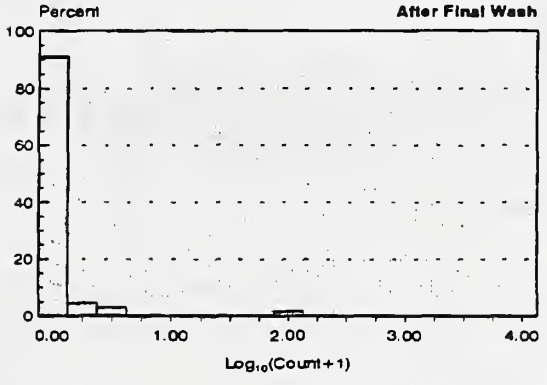


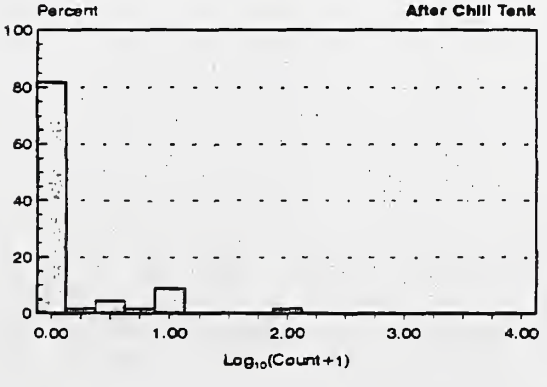
Figure 38. *Salmonella* Distributions - Plant PS3

Phase 1

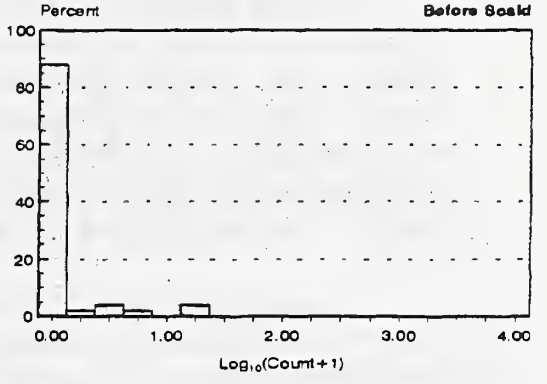


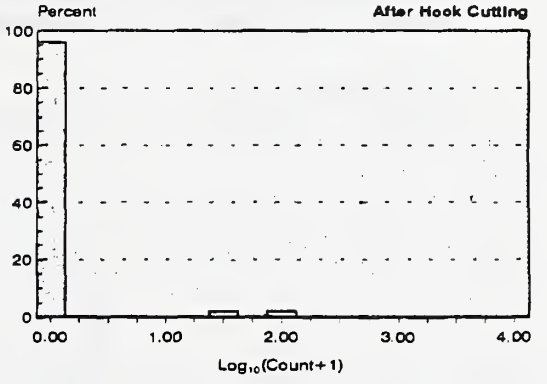


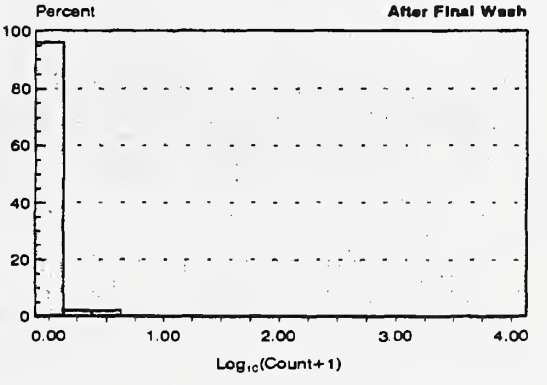


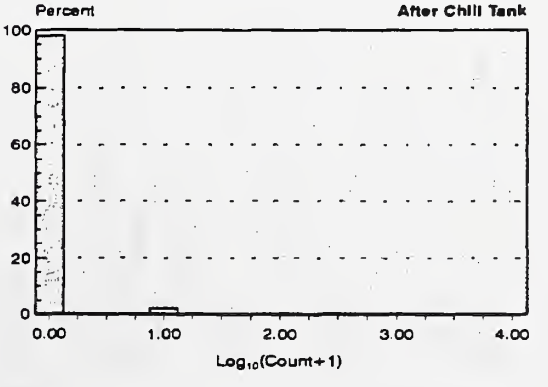


Phase 3







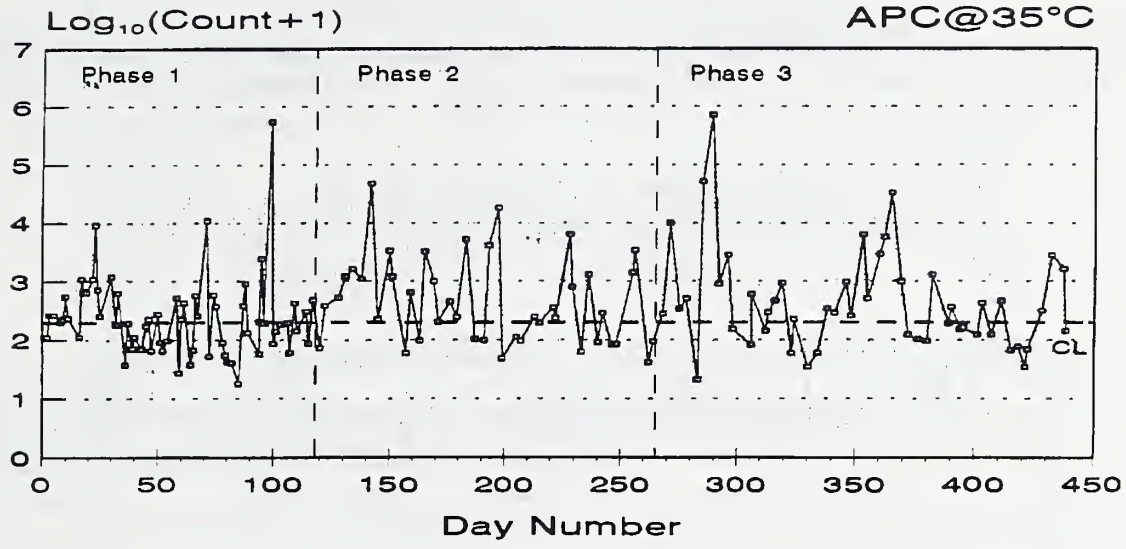


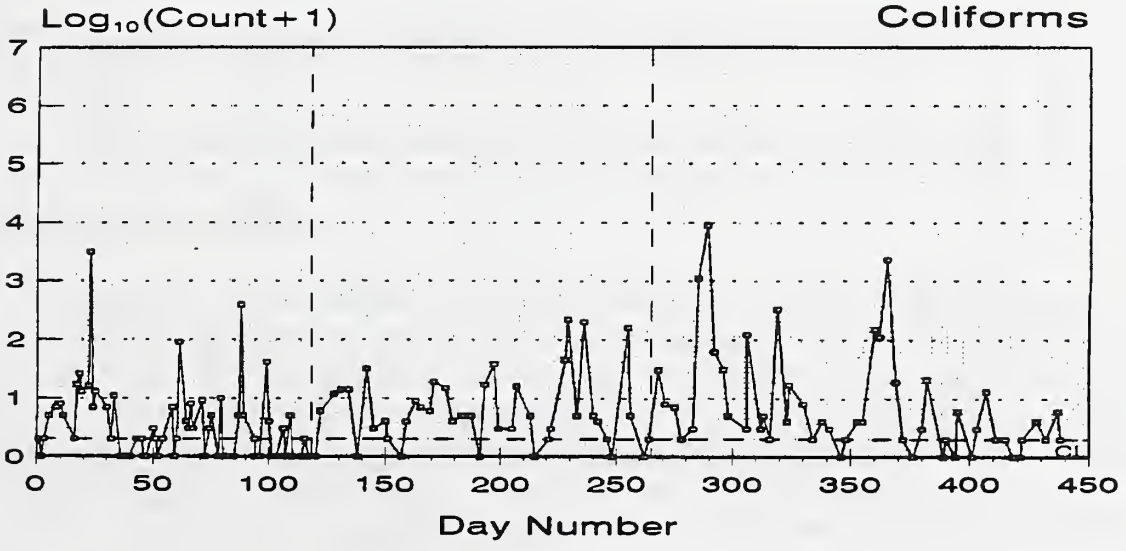
Run charts for the six quantitative microbiology factors are presented in Figure 39. There were sufficient positive results to compute a centerline (CL) from Phase I data for APC @ 35°C , coliforms, *E. coli*, and GFAs. There was a run of points above the centerline for APC @ 35°C and coliforms in Phase I (starting at day 17).

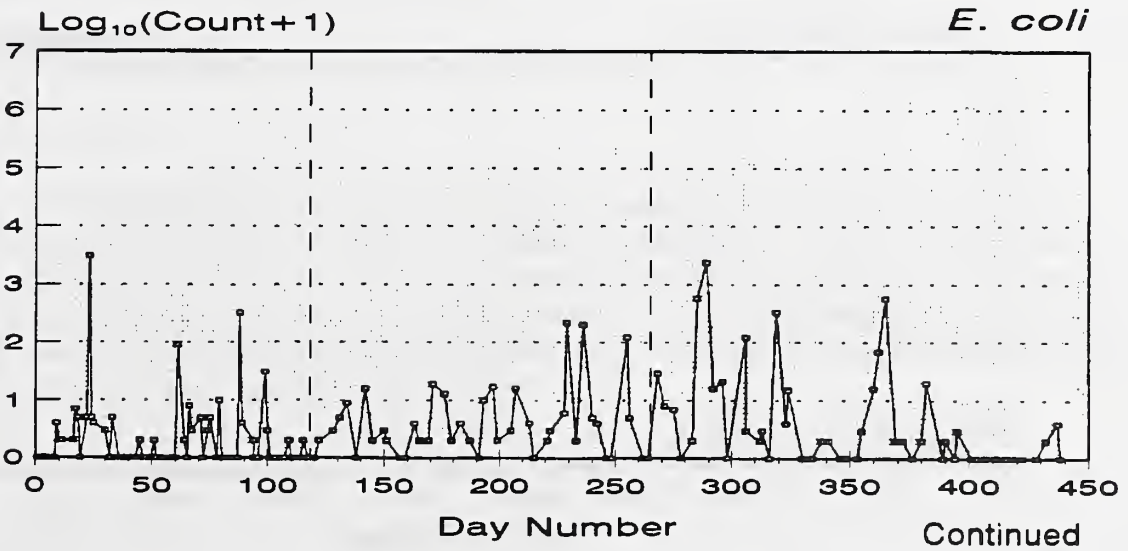
Percent positive *Salmonella* was proposed to be used for process control verification; therefore, percent positives for Phases I and III were compared. The difference, 18.2 percent vs 2.0 percent, was found to be statistically significant ($P<.05$). Figure 38 and Table 44 show that *Salmonella* results for Phase III tended to be lower than those for Phase I. This difference was to be expected, since the *Salmonella* results for the incoming birds in Phase III tended to be lower than those in Phase I. The median chlorine levels were 10 ppm in both Phase I and Phase III and has no explanatory value.

In summary, the HACCP microbiological assessment in Poultry Slaughter Plant PS 3 showed a reduction in *Salmonella* and process instability in Phase I for some microbiology factors. The microbiological profile of the product produced during both phases was indicative of good manufacturing procedures.

Figure 39. Run Charts for Microbiology Data
Poultry Slaughter Plant 3 - After Chill Tank

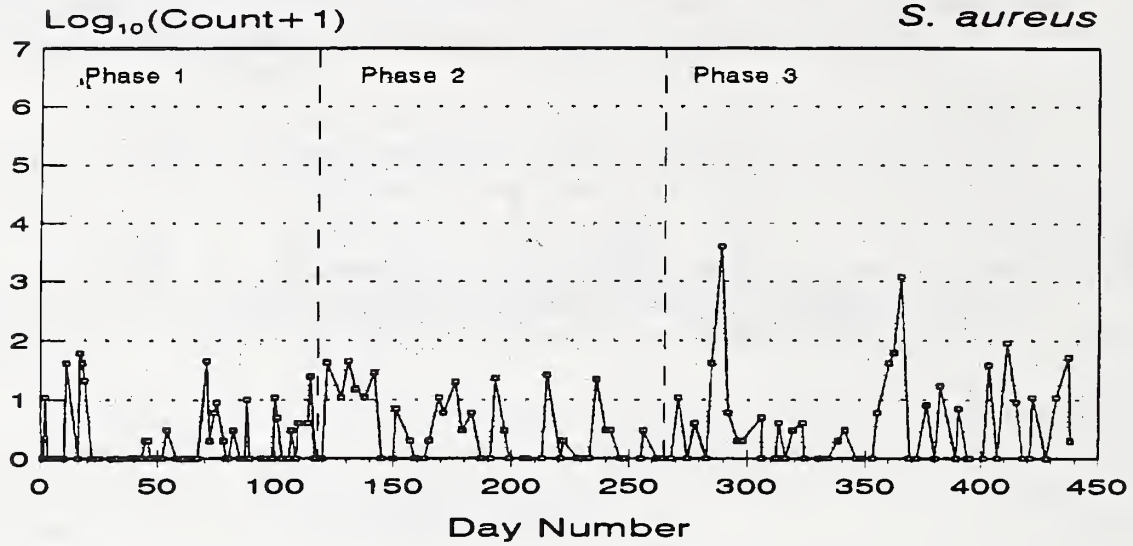


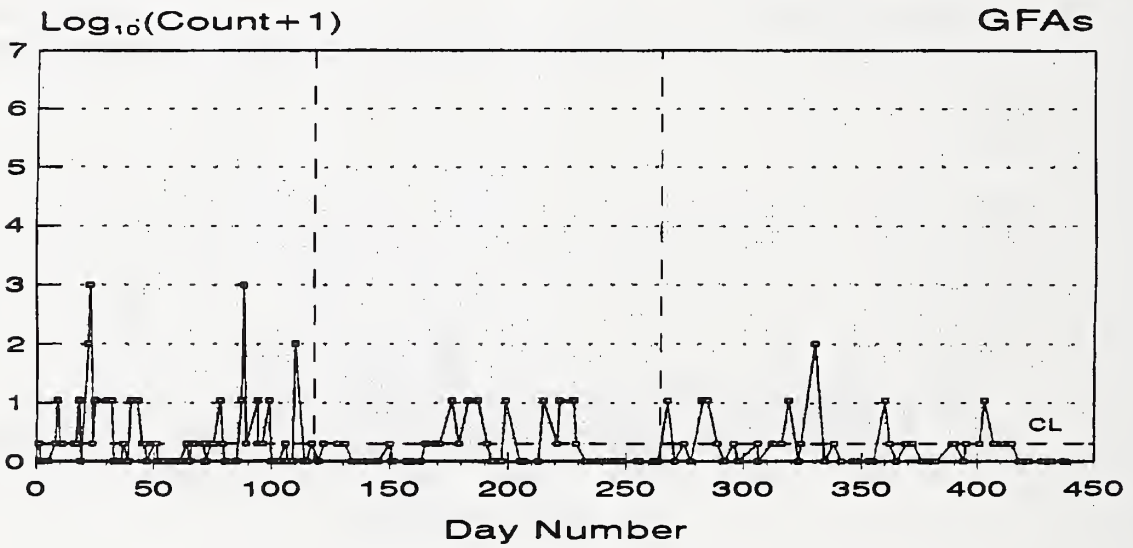


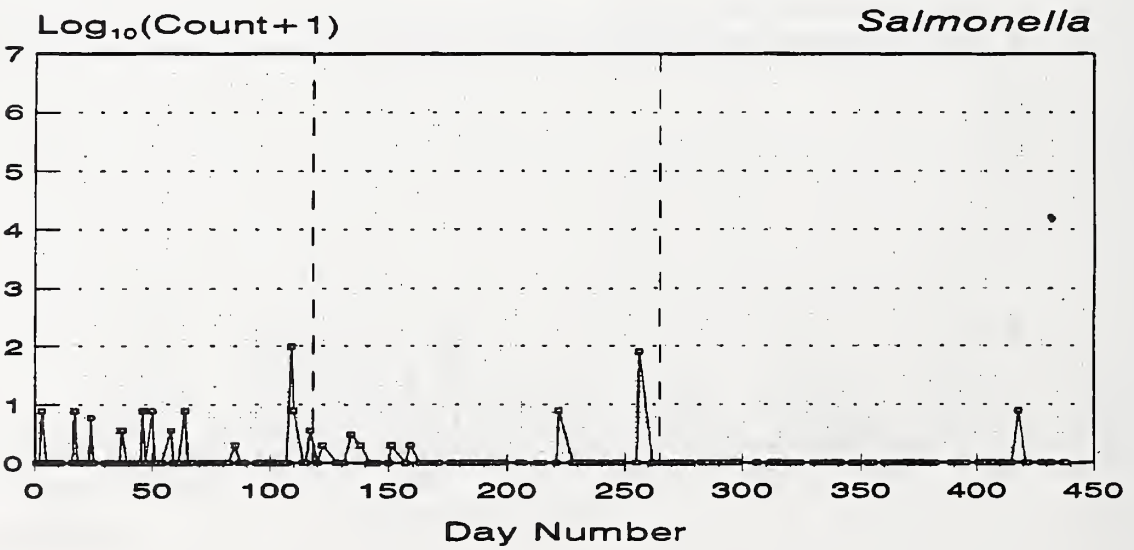


Continued

Figure 39 (continued). Run Charts for Microbiology Data
Poultry Slaughter Plant 3 - After Chill Tank







Physical Factors Analysis:

The intended length of the HACCP study was 13 weeks each for Phase I and Phase III (see Methodology, Chapter 2). Phase II was intended to be a transition period into HACCP plan implementation. Table 45 displays the actual length of the study, in weeks, for each pilot plant.

TABLE 45: LENGTH OF TIME IN WEEKS FOR PHASES I AND III PILOT TESTING FOR PHYSICAL FACTORS AT THE NINE VOLUNTEER PLANTS

PLANT	PHASE I	PHASE III
RF 1	25	27
RF 2	19	26
RF 3	29	29
CS 1	15	25
CS 2	36	26
CS 3	21	26
PS 1	13	26
PS 2	13	27
PS 3	20	26

Variations in Observations:

The number of observations for each data collection task varied within a plant between both Phases, and from plant to plant within each product area. Several factors contribute to this variation, including: the necessity of dual-level scheduling rates for verification tasks (three times a week or once every 2 weeks); varied length of the study for each pilot plant and phase, which ranged from 13 weeks to 36 weeks; changes in plant monitoring plans of the pilot plants; variation in interpretation of data collector instructions detailing when to perform "each occurrence" tasks; and variation in HACCP product availability and plant operations.

Presentation of Results:

Plant control:

A single table for each pilot plant shows qualitatively whether that plant was following an established procedure and/or documenting actions at each control point in each of the physical factors. "Yes" means that an established procedure was present and being followed or that findings were being documented for that particular control point. "No" means that an established procedure was not present or that results were not being documented for that particular control point.

When corrective action was observed by the data collector, he/she determined whether the action taken by plant personnel was appropriate. For example, if the corrective action result is 3/4, that means that the data collector observed corrective action being taken four times and three of the four times the action taken was appropriate.

Agency verification:

The Agency verification measurement is presented together in one table for each product type. The results of the verification data collection tasks are presented in percent compliance and is calculated by dividing the number of yes responses by the total number of observations for the control point. For example, if the verification results for control of time/temperature of heating product is recorded as 100 (30 of 30), then that indicates that the Agency verification for heating product is 100 percent. The data collector measured the actual time/temperature of heating a product 30 times and all 30 observation were in compliance.

Refrigerated Foods Plants:

Plant Control - Refrigerated Foods plant 1 (RF 1)

Established Procedures

Prior to HACCP implementation, RF 1 had established procedures for all but one control point: instrument calibration (see Table 46). The plant established a procedure for calibration.

Documentation

As seen in Table 46, for Phase I, RF 1 documents findings for all control points except two: instrument calibration and heated product flow. After HACCP was implemented, the plant documented instrument calibration results, but not heated product flow.

Corrective Action

Data collection personnel in RF 1 observed the plant taking corrective action 69 times during Phase I and 58 times during Phase III. In every case, it was the appropriate corrective action for a score of 100 percent.

TABLE 46: RF 1 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Refrigerated Food Plant # 1						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION# PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving storage	YES	YES	YES	YES	1/1	
area	YES	YES	YES	YES		
finished product area	YES	YES	YES	YES		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	YES	YES		
non-meat receiving	YES	YES	YES	YES	6/6	
finished product	YES	YES	YES	YES	1/1	
TIME/TEMPERATURE						
heating	YES	YES	YES	YES	2/2	
cooling	YES	YES	YES	YES	3/3	
instrument calib	NO	YES	NO	YES	20/20	1/1
CROSS-CONTAMINATION	YES	YES	YES	YES		1/1
employee hygiene	YES	YES	NO	NO	33/33	47/47
heat product flow						
PACKAGING						
matl acceptable	YES	YES	YES	YES	3/3	2/2
seal integrity	YES	YES	YES	YES		4/4
modified atmos	YES	YES	YES	YES	1/1	2/2
hdlg stmt/dt cde	YES	YES	YES	YES		1/1

(@) If YES - established procedure is present; If NO - no established procedure present

(&) If YES - documents findings; If NO - does not document findings

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
100% (69/69)	100% (58/58)

Plant Control - Refrigerated Foods plant 2 (RF 2)

Established Procedures

Table 47 displays RF 2's results. In Phase I, RF 2 had established procedures for 9 of 15 control points. The plant did not add more procedures after HACCP implementation.

Documentation

Phase I data show RF 2 documented findings for 4 of 15 control points. After HACCP implementation, documentation was added for 4 more control points. The plant did not document findings for 7 control points in Phase III.

Corrective Action

The data collector did not observe RF 2 taking corrective action during Phase I. The plant was observed taking corrective action three times during Phase III, but none of the actions was recorded as appropriate.

TABLE 47: RF 2 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Refrigerated Food Plant # 2						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION# PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving	NO	NO	NO	NO		
raw meat storage	NO	NO	NO	NO		
storage area	YES	YES	YES	YES		
finished product area	YES	YES	YES	YES		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	NO	YES		0/1
non-meat receiving	YES	YES	NO	YES		
product prep	NO	NO	NO	NO		
TIME/TEMPERATURE						
cooking	YES	YES	YES	YES		
cooling	YES	YES	YES	YES		
instrument calib	NO	NO	NO	NO		
CROSS-CONTAMINATION	YES	YES	NO	YES		0/1
employee hygiene	NO	NO	NO	NO		
heat product flow						
PACKAGING						
matl acceptable	YES	YES	NO	YES		
seal integrity	NO	NO	NO	NO		
hdlg stmt/dt cde	YES	YES	NO	NO		0/1

(@) If YES - established procedure is present; If NO - no established procedure present

(&) If YES - documents findings; If NO - does not document findings

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
------	0% (0/3)

Plant Control - Refrigerated Foods plant 3 (RF 3)

The data collector recorded "no" for all tasks performed during a 2-week period in Phase III for RF 3 and commented that "key plant QC personnel on vacation or jury duty." Since the data collector could not accurately measure plant control in the absence of key plant personnel, the data collection results were changed to "not-performed" for this period.

Established Procedures

Baseline data for RF 3 showed the plant had established procedures in place for all but two control points (Table 48). After implementing its HACCP plan, the plant had established procedures at all control points. The established procedure for detection of foreign material in non-meat ingredients was strengthened after implementation of HACCP and reduced the number of dental claims against the company.

Documentation

RF 3 documented 12 of 15 control points during the Baseline Phase. The plant increased documentation to 14 control points in Phase III. They did not document heat product flow under the cross-contamination physical factor.

Corrective Action

During Phase I, RF 3 was observed taking appropriate corrective action 99 percent of the time (460/464). This rate improved to 100 percent in Phase III (292/292).

TABLE 48: RF 3 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Refrigerated Food Plant # 3						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving	YES	YES	YES	YES	28/29	18/18
raw meat storage	YES	YES	YES	YES	33/33	18/18
storage area	YES	YES	YES	YES		
finished product area	YES	YES	YES	YES		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	YES	YES	32/32	19/19
non-meat receiving	YES	YES	NO	YES	30/30	17/17
finished product	NO	YES	NO	YES		18/18
TIME/TEMPERATURE						
heating	YES	YES	YES	YES	35/35	21/21
cooling	YES	YES	YES	YES	58/59	26/26
instrument calib	YES	YES	YES	YES	55/56	36/36
CROSS-CONTAMINATION	YES	YES	YES	YES	97/98	49/49
employee hygiene	NO	YES	NO	NO		19/19
heat product flow						
PACKAGING						
matl acceptable	YES	YES	YES	YES	30/30	19/19
seal integrity	YES	YES	YES	YES	31/31	19/19
hdlg stmt/dt cde	YES	YES	YES	YES	31/31	14/14

(@) If YES - established procedure is present; If NO - no established procedure present

(&) If YES - documents findings; If NO - does not document findings

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
99% (460/464)	100% (292/292)

Agency Verification - RF Plants

Control Point Verification Rates

The total Agency verification rate for the control points ranged from 91.0 percent for the control point covering employee hygiene in Phase III to 100 percent for 11 other control points (Table 49). The control points focused on employee hygiene and foreign material/organoleptic wholesomeness of finished product showed the lowest verification rate at 93.3 percent.

Pilot Plant Verification Rates

The Agency verification rates for the individual pilot plants ranged from 96.3 percent for RF 1 during Phase I to 98.9 percent for RF 1 in Phase III (Table 49). The Agency verification rate increased slightly for RF 1 and RF 3 after HACCP implementation and decreased slightly for RF 2.

TABLE 49: NUMBER AND PERCENTAGE OF OBSERVATIONS FOR AGENCY VERIFICATION OF PHYSICAL FACTORS FOR RF 1, RF 2, and RF 3

AGENCY VERIFICATION
Refrigerated Food Plants

PHYSICAL FACTOR/ control point	RF 1 PHASE #		RF 2 PHASE #		RF 3 PHASE #		CONTROL PT TOTAL PHASE #	
	I	III	I	III	I	III	I	III
TEMPERATURE								
meat recv	100	90	91	100	96	100	95.0	97.5
	10/10	9/10	20/22	25/25	27/28	5/5	57/60	39/40
meat stor	NIP	NIP	100	100	100	100	100	100
			62/62	56/56	37/37	4/4	99/99	60/60
stor area	94	100	100	100	100	100	98.4	100
	15/16	17/17	15/15	36/36	32/32	7/7	62/63	60/60
fin prod	100	100	100	100	100	100	100	100
area	14/14	19/19	26/26	32/32	21/21	7/7	61/61	58/58
FOR MT/ORG								
meat recv	100	100	100	100	100	100	100	100
	7/7	16/16	5/5	3/3	26/26	6/6	38/38	25/25
non-mt recv	86	100	100	100	100	100	97.9	100
	7/8	17/17	13/13	17/17	28/28	4/4	48/49	38/38
prod prep	NIP	NIP	100	100	NIP	NIP	100	100
			52/52	48/48			52/52	48/48
fin prod	100	100	NIP	NIP	99	87	98.6	93.3
	12/12	15/15			77/78	13/15	89/90	28/30
TIME/TEMP								
heating	100	100	100	100	100	100	100	100
	12/12	10/10	15/15	26/26	27/27	15/15	54/54	51/51
cooling	100	100	100	100	100	100	100	100
	22/22	31/31	41/41	56/56	57/57	15/15	120/120	102/102
nutrium	94	97	99	97	97	100	98.9	98.6
calib	118/125	15/15	69/70	33/34	77/79	25/25	89/90	73/73
CROSS-CON								
emp hyg	97	95	94	88	89	98	93.3	91.0
	37/38	41/43	120/128	112/128	50/56	40/41	207/222	193/212
prod flow	100	100	100	98	99	94	99.2	97.7
	12/12	15/15	54/54	54/55	69/70	16/17	135/136	85/87
PACKAGING								
matl accept	94	100	100	100	88	100	93.4	100
	15/16	11/11	20/20	9/9	22/25	11/11	57/61	31/31
seal mtgt	91	100	100	100	95	100	97.7	100
	10/11	14/14	57/57	58/58	21/22	11/11	88/90	83/83
mod atmos	100	100	NIP	NIP	NIP	NIP	100	100
	13/13	16/16					13/13	16/16
hdlg	100	100	100	90	100	100	100	94.5
strnt/dt	10/10	15/15	14/14	28/31	31/31	9/9	55/55	52/55
PLANT TOTALS	96.3	98.9	97.8	96.4	97.6	97.9		
	314/326	261/264	581/594	593/614	602/617	188/192		

NIP - not in HACCP plan (#) % yes #yes/#observations

***Cooked Sausage Plants*:**

Plant Control - Cooked Sausage plant 1 (CS 1)

Established Procedures

Observations during Phase I (Table 50) showed that CS 1 had established procedures in place for 14 of 17 control points. After HACCP implementation, 16 of 17 control points had established procedures. The control point focusing on heated product flow did not have an established procedure.

Documentation

Prior to HACCP implementation, CS 1 documented findings for 11 of 17 control points. During Phase III, the plant documented 16 of 17 control points. The control point focusing on heated product flow was not documented since it did not have an established procedure.

Corrective Action

The data collector observed CS 1 taking corrective action one time during Phase I, and the action was appropriate. During Phase III, CS 1 was observed taking corrective action four times, and on two occasions the action was not appropriate.

Plant Control - Cooked Sausage plant (CS 2)

Established Procedures

As seen in Table 51, CS 2 had all its 18 control points covered by established procedures, both before and after HACCP implementation.

Documentation

During Phase I, CS 2 documented findings for 12 of 18 control points. However, after HACCP implementation no control points were being documented.

Corrective Action

The data collector observed CS 2 taking corrective action 23 times during Phase I, and the data was appropriate in 22 cases. During Phase III the data collector did not observe CS1 taking corrective action.

TABLE 50: CS 1 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Cooked Sausage Food Plant #1						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving	YES	YES	YES	YES		
raw meat storage	NO	YES	NO	YES		
storage area	YES	YES	YES	YES		
product area	NO	YES	NO	YES		
fin prod area	YES	YES	YES	YES		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	YES	YES		
rework	YES	YES	YES	YES		
product prep	YES	YES	YES	YES		
finished product	NO	YES	NO	YES		0/1
REST INGRED CNTL						
formulation	YES	YES	YES	YES		
TIME/TEMP						
heating	YES	YES	YES	YES		
cooling	YES	YES	YES	YES		
instrument calib	YES	YES	YES	YES		
CROSS-CONTAMINATION	YES	YES	YES	YES		1/1
employee hygiene	NO	NO	NO	NO		
heat product flow						
PACKAGING						
matl acceptable	NO	YES	NO	YES		
hdlg stmt/dt cde	YES	YES	NO	YES	1/1	1/2

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
100% (1/1)	50% (2/4)

TABLE 51: CS 2 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Cooked Sausage Food Plant #2						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving	YES	YES	YES	NO		
raw meat storage	YES	YES	NO	NO	1/1	
storage area	YES	YES	NO	NO		
product area	YES	YES	NO	NO		
fin prod area	YES	YES	NO	NO		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	YES	NO	1/1	
non-meat recving	YES	YES	YES	NO		
rework	YES	YES	YES	NO	1/1	
product prep	YES	YES	YES	NO	2/2	
finished product	YES	YES	NO	NO	3/3	
REST INGRED CNTL						
formulation	YES	YES	NO	NO	1/1	
TIME/TEMP						
heating	YES	YES	NO	NO		
cooling	YES	YES	NO	NO		
instrument calib	YES	YES	NO	NO		
CROSS- CONTAMINATION	YES	YES	NO	NO	7/7	
employee hygiene	YES	YES	NO	NO	1/1	
heat product flow						
PACKAGING						
matl acceptable	YES	YES	NO	NO	4/4	
hdlg stmt/dt cde	YES	YES	YES	NO	1/2	

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
96% (22/23)	—

Plant Control - Cooked Sausage plant 3 (CS 3)

The data in Table 52 showed that, prior to HACCP implementation, 12 of 15 control points were covered by established procedures. After HACCP implementation, only the control point covering instrument calibration was not covered by established procedures.

Documentation

Prior to HACCP implementation, CS 3 documented findings for 6 of 15 control points. After HACCP implementation, only one control point -- instrument calibration -- was not documented.

Corrective Action

The data collector observed CS 3 taking corrective action six times during Phase I; the corrective action was appropriate in three instances. During Phase III, CS 3 took corrective action three times; on all occasions none of the actions was appropriate.

Agency Verification - CS Plants

Control Point Verification Rates

As seen in Table 53, the total Agency verification rate for the control points ranged from 95.0 percent to 100 percent. The control point focusing on foreign material/organoleptic wholesomeness of finished product showed the lowest verification rate at 95.0 percent in Phase III. The control point focusing on employee hygiene showed the lowest total Agency verification rate at 95.4 percent in Phase I and 97.5 percent in Phase III.

Pilot Plant Verification Rates

The Agency verification rate for the individual pilot plants ranged from 94.2 percent for CS 2 in Phase I to 99.8 percent for CS 3 in Phase III. The Agency verification rate increased for CS 2 and CS 3 after HACCP implementation and decreased slightly for CS 1.

TABLE 52: CS 3 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Cooked Sausage Food Plant #3						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
TEMPERATURE						
raw meat receiving	NO	YES	NO	YES		0/2
storage area	YES	YES	YES	YES		
fin prod area	YES	YES	YES	YES		
FOR MAT/ORG WHOL						
raw meat receiving	YES	YES	YES	YES	1/1	
non-meat recving	YES	YES	NO	YES		
product prep	YES	YES	NO	YES		0/1
finished product	YES	YES	YES	YES	0/1	
REST INGRED CNTL						
formulation	YES	YES	NO	YES	1/1	
TIME/TEMP						
heating	YES	YES	YES	YES		
cooling	NO	YES	NO	YES		
instrument calib	NO	NO	NO	NO		
CROSS- CONTAMINATION	YES	YES	NO	YES	0/2	
employee hygiene	YES	YES	NO	YES		
heat product flow						
PACKAGING						
matl acceptable	NO	YES	NO	YES		
hdlg stmt/dt cde	YES	YES	YES	YES	1/1	

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
50% (3/6)	0% (0/3)

TABLE 53: NUMBER AND PERCENTAGE OF OBSERVATIONS FOR AGENCY VERIFICATION OF PHYSICAL FACTORS FOR CS 1, CS 2, and CS 3

AGENCY VERIFICATION Cooked Sausage Food Plants								
PHYSICAL FACTOR/ control point	CS 1 PHASE #		CS 2 PHASE #		CS 3 PHASE #		CONTROL PT TOTAL PHASE #	
	I	III	I	III	I	III	I	III
TEMPERATURE								
raw meat recv	100 11/11	100 12/12	83 5/6	100 16/16	100 35/35	— 0/0	98 51/52	100 28/2/
raw meat stor	100 44/44	100 44/44	93 13/14	100 15/15	NIP	NIP	98.2 57/58	100 59/59
storage	100 13/13	96 22/23	100 7/7	100 20/20	100 38/38	100 24/24	100 58/58	98.5 66/67
product prep	100 42/42	100 90/90	92 12/13	100 16/16	100 49/49	100 62/62	99.0 103/104	100 168/168
fin prod area	100 14/14	100 20/20	80 4/5	100 24/24	100 56/56	100 76/76	98.6 74/75	100 120/120
FOR MAT/ORG								
raw meat recv	100 11/11	100 14/14	100 11/11	100 13/13	100 18/18	100 24/24	100 40/40	100 51/51
non-meat rec	NIP	NIP	88 7/8	100 12/12	100 37/37	100 24/24	97.8 44/45	100 36/36
rework	100 14/14	100 14/14	100 8/8	100 2/2	NIP	NIP	100 22/22	100 16/16
product prep	100 20/20	95 19/20	100 11/11	100 11/11	100 46/46	98 58/59	100 77/77	97.6 88/90
finished product	100 46/46	90 45/50	83 5/6	91 10/11	100 61/61	100 61/61	99.0 100/101	95.0 116/122
RESTING CNTL formulation	100 12/12	100 11/11	100 16/16	100 17/17	98 48/49	100 60/60	98.7 76/76	100 88/88
TIME/TEMP								
heating	100 17/17	100 13/13	100 7/7	100 13/13	100 21/21	100 40/40	100 45/45	100 66/66
cooling	100 18/18	100 18/18	100 6/6	100 17/17	98 40/41	100 66/66	98.5 64/65	100 101/101
instrument calib	100 18/18	100 12/12	100 10/10	100 26/26	100 5/5	100 4/4	100 33/33	100 42/42
CROSS-CON								
emp hygiene	94 48/51	89 51/57	89 26/29	100 44/44	97 132/136	99 184/185	95.4 206/216	97.5 279/286
heat prod flow	100 48/48	100 43/43	100 12/12	100 18/18	100 44/44	100 60/60	100 104/104	100 121/121
PACKAGING								
matl accept	100 45/45	100 43/43	100 2/2	100 10/10	100 47/47	100 63/63	100 94/94	100 116/116
hdlg stmt/dt cde	100 15/15	98 82/84	100 9/9	100 17/17	100 52/52	100 64/64	100 76/76	98.7 163/165
PLANT TOTALS	99.3 447/450	97.4 570/585	94.2 179/190	99.7 316/317	99.2 762/768	99.8 934/936		

NIP-not in HACCP plan (#) % yes #yes/#obs

Poultry Slaughter Plants:

Plant Control - Poultry Slaughter plant 1 (PS 1)

Established Procedures

Both before and after implementing HACCP, PS 1 had established procedures in place for all of its control points, as shown in Table 54.

Documentation

Both before and after implementing HACCP, PS 1 documented findings for all of its control points. Data collection results show that the control points covering operational sanitation and scald tank overflow were, respectively, accurately documented at 87 percent (21 of 24) and 80 percent (12 of 15), of the time in Phase I.

Corrective Action

PS 1 was observed taking the appropriate corrective action 99 percent of the time during both Phase I (357/360) and Phase III (757/761).

Plant Control - Poultry Slaughter plant (PS 2)

Established Procedures

As shown in Table 55 PS 2 had established procedures in place for all of its control points, both before and after implementing HACCP. Data collection results show that PS 2 followed its established procedures 69 percent (411 of 600) and 76 percent (649 of 853) of the time in Phases I and III, respectively. Established procedures covering the control points for operational sanitation, midshift rinse, viscera equipment sanitation, and rehang were followed less than 50 percent of the time in one or both of the phases.

Documentation

Prior to HACCP implementation, PS 2 documented findings for 4 of 11 control points. After HACCP implementation, 7 of 11 control points were documented. Documentation covering the control points for scald tank overflow, offline reprocessing, and drawing viscera were added as a result of HACCP implementation.

Corrective Action

PS 2 was observed taking the appropriate corrective action 63 percent (251 of 401) and 37 percent (73 of 195) of the time during Phases I and III, respectively.

TABLE 54: PS 1 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Poultry Slaughter Plant #1						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
SANITATION						
pre-operational	YES	YES	YES	YES	25/25	35/35
operational	YES	YES	YES	YES	23/23	47/48
midshift rinse	YES	YES	YES	YES	27/27	44/46
evisceria equipment	YES	YES	YES	YES	26/26	51/51
scald tank overfl	YES	YES	YES	YES	14/15	53/53
PRODUCT HANDLING						
Product flow	YES	YES	YES	YES	22/22	45/45
offline salvage	YES	YES	YES	YES	25/25	46/46
offline reproc	YES	YES	YES	YES	25/25	42/42
cndmd mat contrl	YES	YES	YES	YES	27/27	51/51
CONTAMINATION						
dressing/handling	YES	YES	YES	YES	13/13	52/52
rehang	YES	YES	YES	YES	25/26	45/46
drawing visce	YES	YES	YES	YES	26/26	47/47
pre-chill	YES	YES	YES	YES	26/26	48/48
post-chill	YES	YES	YES	YES	23/24	46/46
salvage contrl	YES	YES	YES	YES	30/30	105/105

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
99% (357/360)	99% (757/761)

TABLE 55: PS 2 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Poultry Slaughter Plant #2						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
SANITATION						
pre-operational	YES	YES	YES	YES	19/34	1/6
operational	YES*	YES	NO	NO	11/28	0/9
midshift rinse	YES*	YES	NO	NO	6/26	1/9
evisceria equipment	YES*	YES*	NO	NO	12/35	2/19
scald tank overfl	YES	YES	NO	YES	12/15	0/3
PRODUCT HANDLING						
Product flow	YES	YES	NO	NO	23/30	0/9
offline salvage	YES	YES	NO	NO	15/22	0/3
offline reproc	YES	YES	NO	YES	20/27	20/23
cndmd mat contrl	YES	YES	NO	NO	23/24	0/1
CONTAMINATION						
dressing/handling	YES	YES	NO	NO	16/23	2/18
rehang	YES*	YES*	NO	NO	13/35	1/39
drawing visce	YES	YES	NO	YES	19/28	11/15
pre-chill	YES	YES	YES	YES	20/20	12/15
post-chill	YES	YES	YES	YES	23/23	3/4
salvage contrl	YES	YES	YES	YES	19/26	20/22

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
63% (251/401)	37% (73/195)

(*) Followed Established Procedure < 50% of time

Plant Control - Poultry Slaughter plant 3 (PS 3)

Established Procedures

As shown in Table 56, prior to implementing HACCP, PS 3 had established procedures in place for 10 of 15 control points. After implementing HACCP, PS 3 had established procedures for 12 of 15 control points. Established procedures covering pre-operational sanitation and scald tank overflow were added as a result of the HACCP plan.

According to the data collection results, the established procedure for the rehang control point was dropped in Phase III. The established procedure for the control point for evisceration sanitation was followed 74.2 percent (46 of 62) of the time during Phase I.

Documentation

Prior to implementing HACCP, PS 3 documented findings for 10 of 15 control points. After implementing HACCP, documentation was added for two control points -- pre-operational sanitation and scald tank overflow. According to the data collection results, documentation covering rehang was dropped in Phase III.

Corrective Action

PS 3 was observed taking the appropriate corrective action 95 percent (560 of 587) and 99 percent (851 of 854) of the time during Phases I and III, respectively.

Agency Verification - PS Plants

Control Point Verification Rates

The total Agency verification rate for the control points ranged from 19.5% for the drawing viscera in Phase III to 95.2% for product flow in Phase III (Table 57). The control point for drawing viscera showed the lowest verification rate in both Phases I and III, at 23.5% and 19.5%, respectively.

Pilot Plant Verification Rates

The Agency verification rate for the individual Poultry Slaughter plants ranged from 36.5 percent for PS 2 in Phase I to 86.8 percent for PS 1 in Phase III. The total Agency verification rate increased for all three Poultry Slaughter plants after HACCP implementation.

Before implementing HACCP, PS 2 documented findings for 4 of 11 control points. After HACCP implementation, 7 of 11 control points were being documented. Documentation covering the control points for scald tank overflow, offline reprocessing, and drawing viscera were added as a result of HACCP implementation.

TABLE 56: PS 3 OBSERVATION RESULTS OF PLANT CONTROL FOR PHYSICAL FACTORS

PLANT CONTROL Poultry Slaughter Plant #3						
PHYSICAL FACTOR/ control point	EST. PROC. PRESENT @ PHASE		DOCUMENTS FINDINGS & PHASE		CORRECTIVE ACTION # PHASE	
	I	III	I	III	I	III
SANITATION						
pre-operational	NO	YES	NO	YES		57/58
operational	YES	YES	YES	YES	53/55	70/70
midshift rinse	YES	YES	YES	YES	57/61	70/70
evisceria equipment	YES	YES	YES	YES	46/61	75/77
scald tank overfl	NO	YES	NO	YES		76/77
PRODUCT HANDLING						
Product flow	YES	YES	YES	YES	56/58	73/73
offline salvage	NO	NO	NO	NO		
offline reproc	NO	NO	NO	NO		
cndmd mat contrl	YES	YES	YES	YES	56/57	70/70
CONTAMINATION						
dressing/handling	NO	NO	NO	NO		
rehang	YES	NO	YES	NO	5/5	
drawing visce	YES	YES	YES	YES	53/53	74/75
pre-chill	YES	YES	YES	YES	61/62	70/70
post-chill	YES	YES	YES	YES	55/56	70/70
salvage contrl	YES	YES	YES	YES	118/119	146/146

(@) If YES - established procedure present; If NO - no established procedure present

(&) If YES - documents results; If NO - does not document results

(#) number of times appropriate corrective action observed/total number of times corrective action was observed

Appropriate corrective action rate:

Phase I	Phase III
95% (560/587)	99% (851/854)

TABLE 57: NUMBER AND PERCENTAGE OF OBSERVATIONS FOR AGENCY VERIFICATION OF PHYSICAL FACTORS FOR PS 1, PS 2, and PS 3

AGENCY VERIFICATION Poultry Slaughter Plants								
PHYSICAL FACTOR/ control point	PS 1 PHASE		PS 2 PHASE		PS 3 PHASE		CONTROL PT TOTAL PHASE	
	I	III	I	III	I	III	I	III
SANITATION								
pre-operatnl	80	91	0	15	64	45	54.9	46.9
	4/5	10/11	0/11	2/13	35/55	26/57	39/71	38/81
operational	100	100	18	50	50	93	50.0	81.9
	7/7	16/16	2/11	7/14	8/16	13/14	17/34	36/44
midshift rinse	82	64	22	75	46	100	51.5	76.9
	9/11	9/14	2/9	12/16	6/13	9/9	17/33	30/39
evisctn equip	75	73	7	3	69	69	55.9	38.8
	12/16	16/22	1/14	1/32	20/29	9/13	33/59	26/67
scald tnk	79	90	54	85	78	94	70.3	90.2
overflow	26/33	36/40	22/41	46/54	42/54	66/70	90/128	148/164
PROD HANDLING								
Product flow	100	100	82	94	100	90	93.7	95.2
	9/9	14/14	9/11	17/18	12/12	9/10	30/32	40/42
offln salvage	100	100	42	46	21	58	36.2	62.7
	8/8	16/16	5/12	6/13	8/38	42/73	21/58	64/102
offline reproc	100	100	77	67	14	45	40.9	56.6
	11/11	14/14	10/13	14/21	6/42	32/71	27/66	60/106
end mat contl	100	100	90	91	94	83	94.1	91.8
	6/6	15/15	9/10	20/22	17/18	10/12	32/54	45/49
CONTAMINATION								
dress/handling	78	98	13	28	91	94	66.4	75.4
	28/36	53/54	5/36	16/57	54/59	75/80	87/131	144/191
rehang	89	89	4	17	60	35	47.9	39.7
	8/9	17/19	1/21	4/24	26/43	27/78	35/73	48/121
drawing viscr	58	38	15	6	12	15	23.5	19.5
	7/12	11/29	2/13	2/33	3/26	3/20	12/51	16/82
pre-chill	85	69	0	15	13	5	36.1	27.3
	11/13	11/16	0/8	3/20	2/15	1/19	13/36	15/55
post-chill	100	844	95	9	27	9	78.0	33.9
	11/11	16/19	18/19	2/22	3/11	1/15	32/41	19/56
salvg contrl	73	92	16	7	44	51	59.1	75.0
	52/71	93/101	2/12	1/14	14/32	17/33	68/115	111/148
PLANT TOTALS	81.0	86.8	36.5	41.0	55.3	59.2		
	209/258	347/400	88/241	153/373	256/463	340/574		

Physical Factors Summary:

The pilot test results demonstrate that industry, academia, and government can cooperatively develop generic HACCP models to target health and safety issues. Plant-specific plans may be developed from HACCP models and applied to specific meat and poultry product categories. The plan assures that plants control their processes to manage critical areas of food product manufacture. Plants control their processes by adhering to approved established procedures, properly documenting findings, and appropriately correcting of process deviations for each identified process control point.

Verification testing is essential to assess plant control. The study demonstrated that simply adhering to an established procedure and properly documenting findings did not guarantee that a control point was being managed. The study also showed that having an established procedure did not necessarily mean that it was being followed.

QUALITATIVE PLANT DATA:

Assessment of Volunteer Plants' Management Commitment to Control Manufacturing Processes, Quality, and Regulatory Compliance

As part of the overall assessment of the HACCP pilot test, FSIS gathered data through observations to determine the overall regulatory compliance standards of the nine volunteer plants. The analysis provides an overview of the volunteer plants' environment, as well as their management ability and willingness to control the manufacturing processes and their attitudes and commitment to quality and regulatory compliance for health and safety. Eleven categories (See Chapter 2) were identified and scales developed to gauge the plants' and managements' commitment to manufacturing process control, quality, and regulatory compliance.

Each major factor had a number of subfactors or items. The maximum number of both subfactors and items is 112. However, not all items apply to every plant given the product or process used by the plant. The analysis of the information demonstrates the impact of HACCP on the general functioning of the plants. Data were collected during Phases I and III for the 11 factors (see Table 58). A summary of the plant's results is provided, noting when the change occurred from Phase I to Phase III, and the direction of that change for each pilot plant by process type.

FSIS made qualitative assessments by observing plant activities and practices and interviewing plant management and inspection personnel. Observations were recorded on a five point scale -- high, high medium, medium medium, low medium and low. In the analysis, these ratings were converted to a numerical scoring scheme with high receiving a score of one and low receiving a score of five.

TABLE 58: CATEGORIES, NUMBER OF FACTORS, SUBFACTORS AND TOTAL NUMBER OF ITEMS RATED FOR THE QUALITATIVE ASSESSMENT

CATEGORIES	NUMBER OF FACTORS	NUMBER OF SUBFACTORS	TOTAL NUMBER OF ITEMS RATED
1. General Housekeeping	9	-	8
2. Condition of Facilities	9	-	9
3. Employee Hygiene	6	-	9
4. Employee Sanitary Practices	8	-	8
5. Employee Attitudes towards Inspection Requirements	2	7	7
6. Employee Training	2	10	10
7. Management Supervisory Attitudes	2	9	9
8. Management Response to Problem	4	12	12
9. Management Strategies to Prevent Contamination Hazards	2	16	16
10. Product Quality	2	12	12
11. Management Programs and Systems	5	15	15
TOTAL	50	81	112

Refrigerated Foods Plants:

Refrigerated Foods plant 1 (RF 1):

RF 1 was rated on 107 of 112 items or subfactors. Table 59 presents the overall scoring for RF 1. The table highlights what occurred between Phases I and III. The diagonally shaded cells represent the number(s) of items on which no change occurred between the two phases; cells to the right of the shaded area portray positive change (e.g., going from a medium medium rate of 3 to a high medium rating of 2); cells to the left of the shaded area represent a negative change (e.g., going from a medium medium rating of 3 to a low medium rating of 4). The low medium score of 4 indicates the plant is just barely meeting the minimum requirements while the high score of 1 demonstrates the plant greatly exceeds the requirements. The average Phase I score is found in the table at BEFORE AVG. while the average Phase III score is found at AFTER AVG. Below each table is an itemized list of subfactors that changed and the direction of change.

RF 1's average score for Phase I was 2.49 which is between medium medium and high medium. Its Phase III score was 2.46, which is a positive change from Phase I.

Of the 107 items observed, RF 1 had changes in 13 items from Phase I and Phase III observations. There were five ratings going from medium medium to high medium, which demonstrates that the plant exceeds the requirements. For three items, RF 1 moved from high medium to high. In these cases, the initiatives taken by RF 1 for the three factors or subfactors greatly exceeded the regulatory requirements. For five factors, RF 1 went from high medium to medium medium. This change shows that the plant is still soundly meeting the requirements. The major factor areas where negative movement occurred were in General Housekeeping (1 item), Condition of Facilities (2 items), Plant Employee Sanitary Practices (1 item), and Plant Management Measures to Protect Product from Contamination Hazards. (See Table 59 for specific items which showed negative and positive changes).

Refrigerated Foods plant 2 (RF 2):

RF 2 was rated on 91 of the 112 total items. Table 60 displays the scores and lists the items that changed. RF 2 went from a Phase I average score of 2.73 to a Phase III average score of 2.52. These scores show that, overall, the plant was above the medium-medium score of 3 (meeting the regulatory requirements) and moving toward exceeding the requirements. Of the 91 items, RF 2 had positive movement in 19 items, two going from low medium to medium medium, 15 going from medium medium to high medium and two moving from high medium to high. Product Quality and Safety had a total of five items, out of the nine total, shift to the positive items for this factor. General Housekeeping included the next highest number of positive changes, with three.

TABLE 59: QUALITATIVE EVALUATION OF REFRIGERATED FOODS PLANT NUMBER: RF 1

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		2				2	8
3			52	5		57	171
2			5	31	3	39	78
1					9	9	9
SUM	0	0	57	36	12	107	
SCORE	0	8	171	72	12	263	266
						BEFORE AVG.	2.49
					AFTER AVG.	2.46	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 59 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		NEGATIVE CHANGE	
I	5	Sanitation or cleanup staff	2 to 3
II	2	Maintenance of loading docks	2 to 3
II	3	Shipping/receiving areas	2 to 3
IV	5	Sanitary storage of product contact items	2 to 3
IX	21	Management programs prevent contamination from overhead	2 to 3
		POSITIVE CHANGE	
II	4	Plant improvement plan	3 to 2
III	4	Company hygiene policies	2 to 1
III	5	Visibility of policies	2 to 1
III	6	Scope of hygiene policies	2 to 1
VI	2a	Employee inplant refresher training	3 to 2
VII	1a	Management programs encourage and use employee suggestions	3 to 2
VII	1b	Uses TQM	3 to 2
X	1a	Employees trained to take independent action	3 to 2

TABLE 60: QUALITATIVE EVALUATION OF REFRIGERATED FOODS PLANT NUMBER: RF 2

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		1	2			3	12
3			51	15		66	198
2				14	2	16	32
1					6	6	6
SUM	0	1	53	29	8	91	
SCORE	0	4	159	58	8	229	248
						BEFORE AVG.	2.73
					AFTER AVG.	2.52	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 60 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
I	2	Storage of pallets, supplies	4 to 3
I	4	Control of processing debris	3 to 2
I	5	Sanitation or cleanup staff	2 to 1
II	2	Loading docks	3 to 2
II	3	Shipping/receiving areas	3 to 2
III	1	Employee hand washing	3 to 2
III	5	Visibility of policies	4 to 3
VI	1b	Sanitary personal hygiene	3 to 2
VI	1b	Sanitary product handling	3 to 2
VII	1a	Management programs encourage and use employee suggestions	3 to 2
VIII	1	Management action when problems arise	3 to 2
IX	2j	Prevent product contamination with foreign materials	3 to 2
X	1b	Processing procedures designed with multiple safety controls	3 to 2
X	1g	Adequate safety margin built in	3 to 2
X	1g	Management keeps inspection informed	2 to 1
X	2b	Employees take independent action	3 to 2
X	2c	Employees actively involved in production planning	3 to 2
XI	2a	Plant follows TQC procedures	3 to 2
XI	3	Management QA/QC programs	3 to 2

Refrigerated Foods plant 3 (RF 3):

Table 61 displays the scoring for RF 3 during Phases I and III observations. A total of 105 items out of 112 were scored. RF 3's average scores were 2.61 and 2.50 for Phase I and Phase III, respectively. Again, these averages show the plant was above the medium medium rating before operating under HACCP and moved towards a rating of high medium afterward. RF 3 had 14 positive changes and no negative changes. Of the 14 positive changes, 13 were from medium medium to high medium. The factor with the most changes was Plant Management Response to Problems, with five items going from medium medium to high medium.

Refrigerated Foods Plants Summary:

As seen in Table 62, all three RF plants were above medium medium during Phase I and increased their scores during Phase III. The overall Phase I average was 2.61 and the Phase III average was 2.5. Of the 46 changes, 39 were positive with 33 items moving from medium medium to high medium. When the data from all the Refrigerated Foods plants are combined, some trends can be identified. Although each factor category shows at least one change in a subfactor, the factors with the least amount of change are: Plant Employee Attitudes about Inspection; Plant Employee Training; Plant Management Attitudes Toward Employee Supervision; and Plant Management Programs and Systems. The factors showing the greatest amount of change are: Product Quality and Safety; Plant Management Response to Problems; and Plant Measures to Protect Product from Contamination Hazards. Factors associated with day-to-day operations, such as housekeeping, general sanitation, and employee hygiene are in the middle.

Factors dealing with attitudes showed the least amount of change. These are good plants to begin with, and it is difficult to detect attitude changes in the short time period covered by the study. On the other hand, factors dealing more directly with the production of a safe, quality product showed the greatest number of changes. These factors dealt primarily with management initiated programs and actions, and to a lesser degree, employee commitment to producing a wholesome product.

TABLE 61: QUALITATIVE EVALUATION OF REFRIGERATED FOODS PLANT NUMBER: RF 3

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		3				3	12
3			54	13		67	201
2				29	1	30	60
1					5	5	5
SUM	0	0	54	42	6	105	
SCORE	0	12	162	84	6	264	278
						BEFORE AVG.	2.65
					AFTER AVG.	2.51	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 61 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
IV	3	Plant design and layout	3 to 2
II	9	Plant improvement plan	3 to 2
IV	1	Employee practices to prevent cross-contamination	2 to 1
IV	3	Plant traffic patterns	3 to 2
V	1a	Plant records available	3 to 2
VIII	4b	Short-term improvements	3 to 2
VIII	4c	Long-term improvements	3 to 2
VIII	4g	Initiates changes in product safety needs	3 to 2
VIII	4h	Self-motivated to repair facilities	3 to 2
VIII	4i	Commits adequate resources to maintain facilities and produce product	3 to 2
IX	4k	Layout of plant/product flow	3 to 2
IX	2j	Prevent product contamination with foreign materials	3 to 2
XI	2b	Timely update of programs	3 to 2
XI	2c	Laboratory testing	3 to 2

TABLE 62: QUALITATIVE EVALUATION SUMMARY OF THE REFRIGERATED FOODS PLANTS

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		6	2			8	32
3			157	33		190	570
2			5	74	6	85	170
1					20	20	20
SUM	0	6	164	107	26	303	
SCORE	0	24	492	214	26	756	792
						BEFORE AVG.	2.61
					AFTER AVG.	2.50	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ...5 = LOW

Cooked Sausage Plants:

Cooked Sausages plant 1 (CS 1):

CS 1 was rated on 101 of the possible 112 items. The average score of observations during Phase I was 2.66 and 2.44 during Phase III (Table 63). As the averages show, CS 1 was performing on average above medium medium and continued to improve during operations. CS 1 had positive changes for 23 of the 101 items observed. Positive change occurred in ten of the 11 factors, with five changes in Plant Management Measures to Protect Product from Contamination Hazards. The next highest number of changes (three) came in General Housekeeping. CS 1 moved from low medium (just meeting requirements) to medium medium (soundly meeting requirements) on 10 items.

Cooked Sausages plant 2 (CS 2):

Out of the 112 total items, CS 2 was scored on 100 factors. During Phase I its average score was 3.08, which is just below the medium medium rating of soundly meeting requirements (Table 64). The average score of observations made during Phase III improved to 2.90. CS 2 had a total of 17 changes, one of which moved from medium medium to high. This change was for Plant Employee Attitudes about Inspection. Five items moved from low medium to medium medium and 11 moved from medium medium to high medium. Plant Employee Attitudes about Inspection saw movement for five items while Plant Employee Training had the next highest number of factors (four) showing positive movement.

Cooked Sausages plant 3 (CS 3):

CS 3 received scores for 101 of the 112 items (Table 65). Its average score during Phase I was 2.63, which is above the medium medium score. Observations made during Phase III saw an overall improvement to 2.54. There were a total of 16 changes in the observations from Phase I to Phase III. Of the 16 changes, 12 were in a positive direction, while four were in a negative direction. As can be seen in the table, significant progress was made in some areas, while significant decline was made in other areas. Of the four negative changes, three went from a high medium to a low medium (just meeting requirements). On the other hand, four moved in a positive direction from low (not meeting regulatory requirements) to medium medium (soundly meeting regulatory requirements). Three of those four jumped two increments.

The area showing greatest improvement was Management Programs Providing for Employee Training. Management sent one employee to a food processing workshop and provided summer internship to a college student. The scoring reflects poorer results in the factors dealing with quality control and TQC implementation. This fact is partly explained by a change in QC personnel, which adversely affected the plant's QC programs. Positive changes outnumbered negative changes two to one.

TABLE 63: QUALITATIVE EVALUATION OF COOKED SAUSAGES PLANT NUMBER: CS 1

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		1	10			11	44
4			42	11		53	159
2				27	2	29	58
1					8	8	8
SUM	0	1	52	38	10	101	269
SCORE	0	4	156	76	10	246	
						BEFORE AVG.	2.66
					AFTER AVG.	2.44	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 63 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
I	8	Storage of pallets, supplies	4 to 3
I	8	Control of product on floor	3 to 2
I	8	Sanitation or cleanup staff	4 to 2
II	6	Product contact surfaces	3 to 2
II	7	Employee welfare facilities	4 to 3
III	2	Employee clothing	4 to 3
IV	1	Employee practices to prevent cross-contamination	3 to 2
IV	3	Plant traffic patterns	4 to 3
IV	8	Maint.' sanitary precautions	4 to 2
IV	8	Sanitary storage of product contact items	3 to 2
VI	2c	TQM involvement	4 to 3
VII	1b	Management uses TQM	4 to 3
VII	1c	Supervisors use TQM	4 to 3
VIII	4i	Commits adequate resources to maintain facilities and produce product	3 to 2
IX	1b	Product flow inside plant	4 to 3
IX	1b	Employee traffic inside plant	4 to 3
IX	2c	Layout of plant/product flow	4 to 3
IX	2d	Processing equipment maintained	3 to 2
IX	2i	Separation of raw and cooked	3 to 2
X	2d	Employee commitment to safety	3 to 2
8	2d	Employees take independent action	3 to 2
2	2d	Lab results shared with FSIS	2 to 1
XI	2e	Lab records available to FSIS	2 to 1

TABLE 64: QUALITATIVE EVALUATION OF COOKED SAUSAGES PLANT NUMBER: CS 2

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		9	5			14	56
3			68	11	1	80	240
2				6		6	12
1						0	0
SUM	0	9	73	17	1	100	
SCORE	0	36	219	34	1	290	308
						BEFORE AVG.	3.08
					AFTER AVG.	2.90	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 64 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
I	7	Storage of pallets, supplies	4 to 3
III	5	Sanitation or cleanup staff	3 to 2
IV	7	Employee welfare facilities	4 to 3
II	9	Plant improvement plan	3 to 2
V	1b	Management cooperate with inspector concerns or requests	3 to 2
V	1c	Management discusses projects with inspectors during planning	3 to 2
V	1d	Management keeps inspectors informed	3 to 2
V	1e	Management demonstrates commitment to safe, sanitary food production	3 to 1
V	1f	Management works with FSIS management	3 to 2
VI	1a	Sanitary personal hygiene	4 to 3
VI	1e	Sanitary product handling	4 to 3
VI	2a	Employee refresher training	4 to 3
VI	2c	TQM/employee involvement	3 to 2
VII	1b	Management use of TQM	3 to 2
VII	1c	Supervisors use of TQM	3 to 2
VIII	1	Management response to problems	3 to 2
IX	2h	Management ensures use of GMPs	3 to 2

TABLE 65: QUALITATIVE EVALUATION OF COOKED SAUSAGES PLANT NUMBER: CS 3

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5	3	1	3			7	35
4		5	3			8	32
3			33	4	1	38	114
2		3	1	33		38	74
1					11	11	11
SUM	3	9	40	37	12	101	
SCORE	15	36	120	74	12	257	266
						BEFORE AVG.	2.63
					AFTER AVG.	2.54	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 65 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		NEGATIVE CHANGE	
X	1h	TQM implementation	2 to 4
XI	2a	Follows TQC procedures	2 to 4
XI	1	QA/QC programs or systems	2 to 4
XI	4	QA/QC department	2 to 4
XI	5b	Lab staff Training level	1 to 2
		POSITIVE CHANGE	
IV	4	Control of product on floor	3 to 2
II	4	Maintenance of cooler/freezers	3 to 2
III	1	Employee handwashing practices	4 to 3
III	1	Employee protective covering	4 to 3
III	4	Company hygiene policies	3 to 2
IV	1	Employee practices to prevent cross-contamination	3 to 2
IV	8	Sanitary storage of product contact items	4 to 3
VI	2d	Outside training for employees	5 to 3
VI	2e	Encourage employees to become certified food handlers	5 to 3
VI	2f	Continuing education assistance	5 to 4
VII	1a	Management uses employee suggestions	5 to 3

Cooked Sausage Plants Summary:

The combined scores for the three Cooked Sausages plants are presented in Table 66. As displayed in the table, the three plants' average moved from 2.79 during Phase I to 2.63 for Phase III. Collectively, these plants demonstrated the greatest number of changes between Phases I and III. Not every change reflected an improvement, as indicated by the data from CS 3. Some of the changes, both positive and negative, were significant enough to be two scale increments away from the original observation. There is insufficient information to deduce whether these changes are a consequence of HACCP implementation.

In the two plants that showed only positive changes, the rates of change were 23 percent and 17 percent, respectively. They showed improvement in most factors; changes were primarily from one medium rating to the next medium rating. Neither plant had any low scores. The remaining plant presented an enigma, in that it made remarkable progress in some areas, and showed significant decline in others.

When combining the data from all cooked sausage plants, no obvious trends emerge. In fact, some of the factors that showed the greatest change in the refrigerated foods plants show the least amount of change in the cooked sausage plants. The opposite is also true; of the total 302 observations made of the three cooked sausage plants, 165 (55 percent) were recorded at medium medium for Phase III. Scores of medium medium or higher were recorded for 280 (93 percent) of the items with 23 (8 percent) rated as high as opposed to 22 items (7 percent) rated at low medium or below. Three (less than one percent) of the 22 were rated as low.

TABLE 66: QUALITATIVE EVALUATION SUMMARY OF THREE COOKED SAUSAGES PLANTS

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5	3	1	3			7	35
4		15	18			33	132
3			143	26	2	171	513
2		3	1	66	2	72	144
1					19	19	19
SUM	3	19	165	92	23	302	
SCORE	15	76	495	184	23	793	843
						BEFORE AVG.	2.79
					AFTER AVG.	2.63	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

Poultry Slaughter Plants:

Poultry Slaughter plant 1 (PS 1):

The scores for PS 1 on the 99 items observed during Phases I and III are presented in Table 67. The plant showed an improvement in its overall average, moving from 2.96 to 2.88. Of the 99 items observed, nine positive changes and one negative change were observed. Eight items moved from medium medium to high medium, while the remaining positive one moved from low medium to medium medium. The negative change was from high medium to medium medium for Employee Attitude about Inspection. Plant Management Response to Problems items accounted for four of the nine positive changes.

Poultry Slaughter plant 2 (PS 2):

The number of items observed for PS 2 was 105 out of the 112 items (Table 68). The average scores for Phases I and III were 2.48 and 2.45 respectively. These scores represent an average better than medium medium (soundly meets requirements) with movement over half way to the high medium rating (exceeds requirements). Three positive changes (all in Plant Employee Personal Hygiene) were observed, with movement from high medium (exceeds regulatory requirements) to high (greatly exceeds regulatory requirements). For those items that showed no change, PS 2 had 55 percent of its 105 scores at the medium medium rating, 36 percent at medium high and 7 percent at high score.

Poultry Slaughter plant 3 (PS 3):

PS 3 had average scores for the 100 items observed of 3.07 for Phase I and 2.94 for Phase III (See Table 69). This plant showed positive movement from just below a medium medium rating to just above it. A total of 10 positive changes were observed with three items moving from low to medium medium ratings. Six items moved from low medium to medium medium. Items in Plant Employee Personal Hygiene had the most change (4) with two of the four moving from low to medium medium. Of the 100 items observed, 82 were rated at medium medium.

Poultry Slaughter Plants Summary:

Poultry slaughter plants showed the least amount of change between Phases I and III (Table 70), probably because poultry slaughter is conducted under well defined conditions, especially in plants operated under NELS (New Line Speed Inspection System) or SIS (Streamlined Inspection System). Poultry slaughter plants operating under NELS must have an approved partial quality control (PQC) program which identifies critical control points, and is operated by the establishment's quality control personnel.

TABLE 67: QUALITATIVE EVALUATION OF POULTRY SLAUGHTER PLANT NUMBER: PS 1

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4		3	8			8	16
3			79	8		87	261
2			1	7		8	16
1						0	0
SUM	0	3	81	15	0	99	
SCORE	0	12	243	30	0	285	293
						BEFORE AVG.	2.96
					AFTER AVG.	2.88	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 67 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		NEGATIVE CHANGE	
IV	6	Sanitary handling of offal	2 to 3
		POSITIVE CHANGE	
I	7	Microbiological control monitoring program for sanitation	3 to 2
V	1e	Management demonstrates commitment to safe/sanitary food production	3 to 2
V	1f	Management works with FSIS for approval of programs, info, decisions	3 to 2
V	2	Maintenance of inspection office	4 to 3
VIII	2	Planning for emergencies	3 to 2
VIII	4a	Proactive, preventive plans	3 to 2
VIII	4f	Management initiates changes to meet plant needs	3 to 2
VIII	4g	Management initiates changes to meet what inspection sees as safety needs	3 to 2
XI	1	Management programs exceed minimal regulatory requirements	3 to 2

TABLE 68: QUALITATIVE EVALUATION OF POULTRY SLAUGHTER PLANT NUMBER: PS 2

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5						0	0
4						0	0
3			57			57	171
2				38	3	41	82
1					7	7	7
SUM	0	0	57	38	10	105	
SCORE	0	0	171	76	10	257	260
						BEFORE AVG.	2.48
					AFTER AVG.	2.45	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 68 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
III	2	Employee clothing	2 to 1
III	3	Other employee protective coverings	2 to 1
III	4	Company hygiene policies	2 to 2

TABLE 69: QUALITATIVE EVALUATION OF POULTRY SLAUGHTER PLANT NUMBER: PS 3

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5			3			3	15
4		2	6			8	32
3			82	1		83	249
2				5		5	10
1					1	1	1
SUM	0	2	91	6	1	100	
SCORE	0	8	273	12	1	294	307
						BEFORE AVG.	3.07
					AFTER AVG.	2.94	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 69 (CONTINUED)

FACTOR	ITEM NUMBER	DESCRIPTION	SCORE CHANGE
		POSITIVE CHANGE	
I	2	Storage of pallets, supplies	4 to 3
I	5	Sanitation or cleanup staff	3 to 2
I	7	Micro swabbing for sanitation	5 to 3
II	7	Employee welfare facilities	4 to 3
II	1	Employee handwashing practices	5 to 3
III	4	Company hygiene policies	5 to 3
III	5	Visibility of policies	4 to 3
III	6	Scope of hygiene policies	4 to 3
IV	8	Sanitary storage of product contact items	4 to 3
VI	2c	TQM/employee involvement	4 to 3

TABLE 70: QUALITATIVE EVALUATION SUMMARY OF THE POULTRY SLAUGHTER PLANTS

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5			3			3	15
4		5	7			12	48
3			218	9		227	681
4			1	50	3	54	108
1					8	8	8
SUM	0	5	229	59	11	304	
SCORE	0	20	687	118	11	836	860
						BEFORE AVG.	2.83
					AFTER AVG.	2.75	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ...5 = LOW

These programs resemble HACCP to some extent, and the small number of changes observed in the poultry slaughter pilot plant is not surprising. (Two pilot plants are NELS).

The ratings in both Phases I and III clustered predominantly in the medium medium category. No pilot plant received a low rating in any subfactor during Phase III. The total number of elements evaluated ranged from 99 to 105, with the number of changes being either three or ten. The bulk of the changes involved employee hygiene practices and general housekeeping, the exception being a downward move by one plant in the handling of offal. The overall averages for the three plants was 2.83 for Phase I and 2.75 for Phase III.

The plant (PS 2) with the fewest number of changes (three) had an average Phase III score of 2.45, as compared with 2.88 and 2.94 for PS 1 and PS 3, respectively. PS 2 also operated under SIS, rather than NELS, but does, however, use PQC programs on the processing side and practices an informal microbiological monitoring program.

Nine Plant Summary:

The nine plants were observed a total of 909 times for the 11 factors (Table 71). The average Phase I score for the nine plants was 2.74 and represents an above medium medium rating. Phase III showed a positive change for all plants in their overall averages. The nine-plant, Phase III average was 2.62. There were 125 changes, ten of which were in a negative direction (8 percent [10/125]). As can be seen, when change occurred, it was overwhelmingly in a positive direction. Of the total 909 observations, nearly 13 percent (115) were recorded as positive changes. The medium medium rating was observed 518 times (57 percent), while change to the medium medium rating was observed an additional 40 times (33 in a positive direction and seven in a negative direction). As seen in the Phase III, 60 of the 909 items (7 percent) were scored as high, which represents activities that greatly exceed requirements. Only 3 items were rated a low.

Table 72 summarizes the rating changes for items of the 11 factors observed at the nine plants. Negative changes are denoted by a bracket [ ]. All the factors showed some improvement. The data are insufficient to draw conclusions concerning the impact of HACCP on the level of regulatory compliance. In general, plants improved in their ratings. Improvements in General Housekeeping were widespread and were much easier to identify than improvements in Plant Management Attitudes Toward Employee Supervision because intangible issues are difficult to quantify. In general, the factors that deal more directly with issues encompassed by the regulations showed greater number of changes than those factors that dealt with intangible issues.

TABLE 71: QUALITATIVE EVALUATION SUMMARY OF REFRIGERATED FOODS, COOKED SAUSAGES, AND POULTRY SLAUGHTER PLANTS (3 PLANTS FOR EACH HACCP AREA)

PHASE I SCORE	PHASE III SCORE *					SUM	SCORE
N	5	4	3	2	1		
5	3	1	6			10	50
4		26	27			53	212
3			518	68	2	588	1764
2		3	7	190	11	211	422
1					47	47	47
SUM	3	30	558	258	60	909	
SCORE	15	120	1674	516	60	2385	2495
						BEFORE AVG.	2.74
					AFTER AVG.	2.62	

* 1 = HIGH; 2 = HIGH MEDIUM; 3 = MEDIUM MEDIUM; ... 5 = LOW

TABLE 72: SUMMARY OF CHANGES FOR THE 11 FACTORS OBSERVED AT THE NINE HACCP VOLUNTEER PLANTS

	Changes in factors from 1st to 2nd visit								
	RF 1	RF 2	RF 3	CS 1	CS 2	CS 3	PS 1	PS 2	PS 3
I	[1]	3	1	1	2	1	1		3
II	1[2]	2	1	2	2	1			1
III	3	2		1		3		3	3
IV	[1]		2	1		2	[1]		1
V			1		5		3		
VI	1	2		1	1	3			1
VII	2	1		2	2	1			
VIII		1	5	1	1		1		
IX	[1]	1	2	5	1				
X	1	5		1		[1]			
XI		2	2	2		[4]	1		

[ ] - denotes a negative change

HACCP Pilot Plant Training:

This section discusses the results of the survey administered to participants who received training at the pilot plants (or local training sites) shortly before Phase II HACCP Implementation activities began. As stated in the Methodology section, the primary audience for the training was FSIS inspection personnel. Participants included: from FSIS, inspectors, relief inspectors, circuit supervisors, area officials, regional officials, and HACCP data collectors; and plant managers, production supervisors, and QC/QA staff from the plants.

The analysis presents the aggregate totals for all 101 participants from the eight training sessions. No assessment was made for the training at PS 1 because the survey data sheets were not collected. Table 73 shows the demographics of respondents by process category.

TABLE 73: CATEGORY AND NUMBER OF RESPONDENTS FOR THE HACCP PILOT TRAINING SURVEY

CATEGORY	NUMBER									TOTAL	PERCENT OF TOTAL
	REFRIGERATED FOODS			COOKED SAUSAGE			POULTRY SLAUGHTER				
	1	2	3	1	2	3	1	2	1		
Meat & Poultry Industry	0	0	4	9	1	3	0	7	6	30	30
FSIS	12	5	10	7	10	7	0	10	9	70	70

Table 74 summarizes the responses for assessing usefulness of the training material used. The plant-specific plan module was rated as being useful/or very useful by seven out of every eight participants (87 percent). The modules for monitoring and evaluation for both implementation and operational phases were also found useful by slightly more than eight out of every ten participants. With respect to understanding one's role (My role), nearly seven out of every eight respondents thought the training was useful or very useful. Overall, a significant number (more than seven out of every ten) rated the material as being equal to or better than useful. In only one area (Inspector Assignment Schedule) did more than 20 percent of respondent give a rating below the useful level.

Besides rating the usefulness of the training materials, participants were asked to rate the effectiveness of the training materials. Table 75 summarizes their responses to the 14 items. For all but for one of the 14 items (Process Deficiency Record), a minimum of eight out of every ten respondents felt the materials were effective. As with the usefulness of the material, the vast majority of respondents rated the effectiveness of

TABLE 74: RESPONSES AND PERCENTAGES FOR TRAINING MODULE'S USEFULNESS RATING

Module	Usefulness of Training Modules				Total Response
	Not Useful/Effective	Somewhat Useful/Effective	Useful/Effective	Very Useful/Effective	
HACCP Study	2 (2%)	11 (11%)	47 (48%)	38 (39%)	98
Plant-Specific Plan		9 (9%)	45 (45%)	47 (47%)	101
PBIS/HACCP relationship*	1 (1%)	10 (11%)	27 (39%)	28 (41%)	69
Supplemental Inspection System Guide*	1 (2%)	9 (13%)	24 (36%)	33 (49%)	67
HACCP Task Plan**	1 (3%)	1 (3%)	14 (44%)	16 (50%)	32
Inspector Assignment Schedule**	8 (12%)	13 (14%)	29 (42%)	21 (30%)	69
HACCP Inspection Task Schedule**		2 (7%)	12 (39%)	17 (55%)	31
Process Deficiency Record**	1 (2%)	14 (21%)	27 (40%)	26 (38%)	68
Sanitation Report**		3 (9%)	15 (47%)	14 (44%)	32
Monitoring (during Phase II)	1 (1%)	13 (14%)	55 (57%)	27 (28%)	91
Evaluation (during Phase II)	1 (1%)	10 (11%)	56 (58%)	27 (28%)	97
Monitoring (during Phase III)	1 (1%)	10 (11%)	52 (55%)	32 (34%)	95
Evaluation (during Phase III)	1 (1%)	13 (14%)	51 (54%)	30 (32%)	95
My role	2 (2%)	11 (12%)	43 (46%)	37 (40%)	93

* Numbers and percents are for Refrigerated Foods and Cooked Sausage pilot plant respondents.

** Numbers and percents are for Poultry Slaughter pilot plants.

TABLE 75: RESPONSE AND PERCENTAGES FOR TRAINING MATERIAL'S EFFECTIVENESS RATING

Module	Effectiveness Usefulness of Training Modules				Total Responses
	Not Useful/Effective	Somewhat Useful/Effective	Useful/Effective	Very Useful/Effective	
HACCP Study	1 (1%)	10 (10%)	46 (47%)	41 (42%)	98
Plant-Specific Plan		11 (11%)	39 (39%)	50 (50%)	100
PBIS/HACCP relationship*	1 (2%)	10 (15%)	29 (43%)	28 (41%)	68
Supplemental Inspection System Guide*	1 (2%)	9 (13%)	23 (34%)	34 (51%)	67
HACCP Task Plan**		1 (3%)	16 (50%)	15 (47%)	32
Inspector Assignment Schedule*	4 (6%)	9 (13%)	34 (50%)	21 (31%)	68
HACCP Inspection Task Schedule**			15 (48%)	16 (52%)	31
Process Deficiency Record*	1 (2%)	14 (21%)	23 (34%)	30 (44%)	68
Sanitation Report**	1 (3%)	3 (9%)	15 (47%)	13 (41%)	32
Monitoring (during Phase II)	1 (1%)	14 (15%)	52 (54%)	29 (30%)	96
Evaluation (during Phase II)		16 (17%)	54 (57%)	25 (26%)	95
Monitoring (during Phase III)		13 (14%)	51 (55%)	29 (31%)	93
Evaluation (during Phase III)		14 (15%)	51 (55%)	28 (30%)	93
My role		12 (14%)	44 (50%)	32 (36%)	

* Numbers and percents are for Refrigerated Foods and Cooked Sausage pilot plant respondents.

** Numbers and percents are for Poultry Slaughter pilot plants.

the materials for both implementation and operational phases as effective or higher (i.e, over 80 percent in 13 of 14 items).

Fifty-seven percent of the respondents rated the delivery methods used (lecture, hands-on workshops, etc.) as the best way to cover the subject matter for each module. Forty percent rated the delivery methods the best for some modules. Suggestions included providing a pre-informational package, more hands-on workshops, videotapes, telephone hotlines, and visits from Regional Coordinators. Nine out of every ten respondents rated the trainers as effective or very effective. ("Trainers" included: Special Team presenters; plant presenters; and others, such as Processing Inspector Coordinators (PIC's); area office staff, and Washington staff). Nearly seven out of every eight respondents (86 percent) felt that the subjects presented were appropriate. Additional subjects suggested by respondents were more basic HACCP information, more real plant problems that occur during operations, review of microbiological test results, and more in-depth training on monitoring. Some respondents suggested deleting or reducing the repetition of previous HACCP history, review of HACCP generic plans, time spent on inspectors' duties, and the time spent on each topic.

Headquarters and Regional Coordinator observers of the training sessions agreed that the trainers were knowledgeable about the subject matter and presented the topics in a professional manner. They gave feedback on notebooks, handouts, style, etc., to the trainers after each session. For example, at one of the early training sessions, it was suggested that handouts and reference material should not be given to participants until necessary, to prevent potential confusion due to reading ahead during presentations. At subsequent sessions, the handouts were distributed at the appropriate times.

The observers also reported that the subject matter (modules) and material were appropriate for the participants. Regional Coordinators supported these observations later during monitoring visits. Inspection personnel were able to perform duties and understood their responsibilities in the pilot plants. Little remedial training was necessary for inspection employees. Plant personnel demonstrated an adequate working knowledge of HACCP concepts and principles at most of the pilot plants. It should be noted that, at three of the pilot plants, Agency personnel (non-inspection) spent significant time working with responsible plant personnel to develop acceptable plant-specific HACCP plans.

Overall, the training was believed to be a success in meeting its objectives by providing participants with an understanding of the seven HACCP principles, the generic versus plant-specific plans, the relationship between HACCP and the PBIS as operated in the pilot plants, and the HACCP study.

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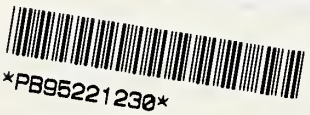

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